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TRANSCRIPT OF PROCEEDINGS

FOOD AND DRUG ADMINISTRATION

CONSUMER ROUNDTABLE ON

CONSUMER PROTECTION PRIORITIES

Pages 1 through 217

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FOOD AND DRUG ADMINISTRATION

CONSUMER ROUNDTABLE ON

CONSUMER PROTECTION PRIORITIES

Wednesday, December 13, 2000

9:17 a.m.

Hubert Humphrey Building
Penthouse Conference Room
200 Independence Avenue, S.W.
Washington, D.C.

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C O N T E N T S

C O N T E N T S (Cont'd.)

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P R O C E E D I N G S

OPENING

MR. BARNETT: If everyone is seated, I think we'll start the meeting. I want to welcome you to this consumer roundtable meeting. I'm Mark Barnett with the Food and Drug Administration and I'll be serving as your moderator this morning and this afternoon. Seated with me is someone who needs no introduction for most of you. She's Dr. Jane Henney, Commissioner of the Food and Drug Administration.

Before we hear from Dr. Henney, let me just say in a very simple way that the purpose of this meeting is to be sure or help be sure that consumers have a say in what FDA does and how it spends its money. Now, obviously, this agency doesn't have complete flexibility in what it does. We are constrained by the mandates of the laws that we enforce and by the Congress. But within that mandate, we do, in fact, set priorities, priorities in our research efforts, our education, in the way we enforce the law, in the way we approve products before they're marketed, and in the way we monitor them after they're marked, and, of course, that's where this meeting comes in because it gives you the opportunity to affect that priority-setting process and let us know what you think we should be doing.

A couple of housekeeping things. Is there anyone here, and let me have your hand, who would need the services

of a sign language interpreter. I see no hands? Okay, fine.

The other bit of housekeeping is the usual thing you hear about cell phones and beepers. Put them on "vibrate" or turn them off, if you would.

Dr. Henney, let's begin by talking about the purpose of the meeting. As I stated it and as it's in the Federal Register, it says something about getting input from consumers about the direction FDA takes in its planning process, but that's the input part of it. There's an output part, too, I would think, and that is getting consumer groups to work with the agency in getting the job done. How important is that?

DR. HENNEY: Well, Mark, it's very important, but let me back up and just say a few things about consumer engagement with this agency. Even though we're almost on the verge of celebrating our 100th birthday--that will happen in 2006, so it's coming fairly close--this is one of the oldest consumer protection agencies in the government, and so I think both our history in terms of--and pride in our organization comes from our mission of consumer protection and public health promotion. It's also written very clearly in the mission statement of this agency.

I think that some of the ways in which the agency over time, over the course of this last century, has tried

to actively engage consumers in the business of the agency has been in a number of ways. One was we were the first agency to really open up the advisory committee process, not just to the technical experts but to the public, as well, and to have open public meetings where anyone could comment on the business under consideration at that point. We've done our business by open comment rulemaking. And I think the other thing that we feel is very important in our own history is that we were one of the first agencies in the Federal Government to have an Office of Consumer Affairs.

But even with that history, I think over the course of the last two years, although I've seen many of the faces that are here in this audience today, I think that we need to have even more and better ways in which we can engage consumers and the public in the business of the agency, and one of the most important parts of engagement is in our planning process.

We are just on the verge of starting that internally, that budget planning process within the agency, so at this point in time, we wanted to hear from consumers and from consumer groups. I know that over the course of the past year you've attended many stakeholders' meetings, but we wanted to have a meeting really just for you, to hear your voice in this. I think we want to not only do this today but keep doing this in an effort to keep increasing

our transparency as an organization about what we do and why our decisions are made in the way that they are and include your voices in that process. And third, we're looking for projects, quite frankly, that can advance our shared vision of the promotion of public health and the protection of consumers through cooperative projects.

So if we hear some of those kinds of ideas today, either projects, ways in which we can increase our transparency, and things that you think that we need to consider as we inside the agency go into our internal planning process for the subsequent year's budget, those are the kind of things that we would particularly like to hear.

MR. BARNETT: And shared projects is one of the things that you've stressed the most in terms of priorities, not just with consumers but with other stakeholders, as well, and one of your favorite words there is the old word--

DR. HENNEY: Leveraging.

MR. BARNETT: --leveraging, right. Say a little bit about leveraging.

DR. HENNEY: This is something that's not necessarily new to the agency, but I think our emphasis on it is. It goes back to way before my time when Archimedes once said, give me a place to stand and I can move the world, and he was talking about being able to move the world with a lever, a strong position and effort against what

would seem like forces that are immovable.

I think with the vast amount of products under our jurisdiction, with the kind of mandate that FDA has, and the resource limitations that we have both in terms of our own staff and others, we need to look for ways in which we can, through leveraging also the mission of other agencies or organizations who have like goals, to get our cooperative work together, get us more emphasis in terms of improving the public health. That's what we're looking for.

MR. BARNETT: Is your stress on leveraging really because of budget constraints? I mean, if the FDA doesn't have enough people and dollars to do everything it could do, then obviously working with others is important. But suppose we had more money and more people. Would you still be talking about this?

DR. HENNEY: It's my belief that we will always need others in order to do our work, and let me give you a simple example, although it would be nice to have more money, Mark. I wouldn't give that option away.

But even if we had all of the resources imaginable, I think that there are still things that we could never hire into the agency or we would never have access to. Some of those kind of things are the intellectual capital that resides in different pockets of different organizations across this country that we may need

periodically, but not full time, and there are certainly groups--I'm sure that many of them are represented in this room--that can reach other people with messages in ways we could never do, even if we had a vast amount of money, because their credibility with those memberships or those groups is far greater than a government agency. While we have our own credibility, in part, people that work at the grassroots who have either a similar kind of diseases or similar interests can reach people in ways that we can't.

And so even if we had a vast amount of resources, I think that we still need to be looking for opportunities in which our work can be maximized by working with others.

MR. BARNETT: Another big word in your priority list is the "S" word and that is science and improving the science base of the FDA. If you went out and did a survey of people on the street and you said, tell me the first thing that comes into your minds when you think about health science and the Federal Government, probably FDA wouldn't be first. They may say NIH and so on. But FDA is a science organization. Why do you think it's that important to keep the science base as strong as possible?

DR. HENNEY: My emphasis on science is because we use scientific evidence to ground all of our decisions, and if we aren't well skilled in interpreting and knowing what strong scientific evidence is, our decisions will either be

slow because they'll be very risk adverse or they'll be wrong. And so keeping at the top of our game scientifically, I believe is very important.

I do think it's interesting, one thing you brought up about how well known this agency is. When Research America conducted some of their surveys a few years ago, 80 percent of Americans can identify FDA as the place where new drugs and devices are approved. They don't associate that necessarily with science in the NIH sense.

I think the other surveys that have been conducted that have been particularly interesting that also connect this science issue is one done by the Pew Foundation this past spring and it was done of all Federal regulatory agencies, asking different groups--consumers, patients, health professionals, and regulatory officers of much of our regulated industry--what kind of confidence do you have in this particular agency? And remember, this was done of a wide variety of Federal regulatory agencies. The confidence level there was somewhere between 75 and 80-some percent for this agency of all of those diverse groups. They had confidence in our decision making.

The other thing in that survey that they asked was, do you believe that the agency makes its decisions based on science? Again, same kind of percentages, 75 to roughly 83 or 84 percent believe that FDA used science in

its decision making process. So the linkage there of trust and confidence and using the evidence of science to ground decision making, it doesn't mean that other considerations don't at some times get melded into the mix. But the grounding for all decision making being in science is very tightly linked to the trust and the credibility people have in an agency.

MR. BARNETT: The role of consumers in affecting the health care system and in their own health care is certainly changing a great deal. It's changed over the past decade or so. Talk a little bit, if you would, about how that affects the FDA and the FDA's interaction with consumers and the FDA's role.

DR. HENNEY: Well, I think that the activism by consumers is a very healthy sign, but it also means that we have got to shift some of our emphasis on what we do as an agency. The consumers desire for information, wanting to be involved in their own care, having access through the Internet to all kinds of facts and figures, means we need to be better in our outreach efforts, we need to be better in terms of signaling what is quality information, we need to be engaged in a different kind of way than we have been in the past, which has been much more paternalistic, I would say, in terms of saying, we'll tell you what you need to know and you'd better believe us. I don't think that that's

going to be a right position to be in going forward.

MR. BARNETT: Do you view the FDA as helping people to sift through the tremendous amount of information that they have available, the Internet, for example?

DR. HENNEY: Well, one way we do that is by our own website, in terms of posting information. We also have much on our website to try to help consumers in terms of discerning other information that's on the Internet or information about a variety of products that they might want to take into their physician and say, here are all these products that may be used for this particular operation. He seems to have pros and cons. Tell me about it. So we're trying to provide both identifiers for quality information and also prompters for the consumer or the patient to be helpful in engagement with their health professionals.

MR. BARNETT: I know you're going to be listening very carefully to what people say today, but beyond that, how committed are you to actually acting on what you hear, using people's ideas in developing the FDA's plans?

DR. HENNEY: I think that we don't take scheduling a meeting like this lightly. We don't take having all of the senior staff here to make not only presentations but really to be present to listen to you and then intend to turn a deaf ear. We intend to take what you say, see how we can use it. I can't make the promise that everything that

we hear today, we'll be able to act on or do, but you certainly have our sincere desire to hear what's on your mind, and as we can, work it into our planning process. And I would also say that we don't intend for this to be the last time that we have engagement with you.

MR. BARNETT: I think many people, consumers and consumer groups, look upon the FDA planning process as something that's the FDA's business, something that's kind of internal to the agency. Is it important, though, that folks on the outside understand that process in order to most effectively be able to work with the agency?

DR. HENNEY: Well, I don't think that we're different than any other Federal agency or any other organization that people have dealt with. The more you know about an organization's working, the more successful you are at understanding what's going on.

So writing one letter or saying one thing or waving an issue before an agency may have a moment's notice, but I think your trying to understand what we do on a day-to-day basis and when and how we make our decisions will be very helpful to you to know how to move the issues that are important to you forward. I worked at the NIH for nine years and know very well that the groups that are very effective in terms of dealing with an organization, be it a health organization or a Commerce Department or anybody, are

the people who really understand the processes all through the year.

MR. BARNETT: Thanks for setting the stage for this meeting, and now let me explain a little bit about the format we're going to use today. We're going to ask the director of each of the FDA centers to present that center's priorities for the coming year or years. Those presentations will take about 15 minutes.

Then after that, I'm going to ask the representative of a consumer organization with a particular interest in that topic to respond to what the center director said and to make suggestions about what that organization believes the center should be doing, and that should take about another 15 minutes.

Then in the time remaining before we go to the next center, I'll open the floor to questions and comments from the audience, and I'm going to give priority to consumer groups and consumers because this is, after all, a consumer meeting.

So at this point, I was going to say I'll call up, but you're here already, and Dr. Henney and I will move over so that you can see what's on the screen, and our first center is the Center for Biologics Evaluation and Research

the Center for Medical Consumer and Health Care Information. So I'll ask Dr. Zoon to take over.

I'm going to issue a gentle reminder to both presenters in all cases when the 15-minute mark is about to come up. The weatherman says there's going to be an ice storm this afternoon, so we're impelled or we're motivated to actually close this meeting at the prescribed time.

Dr. Zoon?

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

DR. ZOON: Thank you, Mark, thank you, Dr. Henney, and thank you, Art, for coming. I'm just going to stand up a minute and say hi because I know many of you are in the back and can't see very well, so I want you to see who's talking up here. I appreciate the opportunity to be here today.

I'm really very pleased that the agency has put together such a wonderful program and asked me to participate. Particularly with the great deal of topics today, biologics will also present themselves in a way that I will explain to you, because sometimes people ask me, what is a biologic?

But I'll start out, if I could have the next slide, please, is to just give you the mission of the Center for Biologics. The mission of the Center for Biologics is to protect and enhance the public health through the

regulation of biological products, including blood, vaccines, therapeutics, and related drugs and devices, according to statutory authorities. The regulation of these products is founded on science and law to ensure their purity, potency, safety, efficacy, and availability. And I'll start out with that because that's the fundamental premise upon which we act.

I'm going to sit down now, and hopefully everybody will be able to see the slides. Please don't hesitate at the end when we're done to ask questions. If I could have the next slide, please.

What is a biologic? Well, biologic encompasses many types of products, many of which you in the room have experience with on a day-to-day basis, and these include vaccines. All of us, or many of us as parents or recipients of vaccines to protect children, to protect us against adult diseases, have a great deal of interaction and experience with these products. Allergenic extracts, which are another product, these are very traditional products, as is blood and blood safety and blood-derived products. Our center has responsibility for these.

Devices related to blood safety and biological product safety are under the purview of CBER, and more recently the biotechnology products, including monoclonal antibodies, recombinant DNA-derived proteins, new thing such

as somatic cell and gene therapies, xenotransplantation, and more recently, embarking in tissue products.

So this is a large portfolio. Biotechnology actually cross-cuts all our products and has been integral into the availability of many products that in the past have not been present.

The next slide just gives the concepts. We call these our Olympic rings of regulation, and I like that always in an Olympic year, but they include science and law throughout our evaluation with the eye toward public health impacts. And these include review, review of documents such as investigational new drug applications, license applications, looking over adverse events, looking over labeling for products, materials that go out to private citizens or to doctors to make sure they have the right information in them.

We do regulatory research to ensure product safety or to develop new guidances to ensure that--to facilitate the advance of new technology.

Surveillance is a very important part of our program. This is looking at adverse events, making sure that we have our fingers on the pulse of what the safety parameters of our products are, both pre- and post-marketing.

Policy development is very important, making sure

that there's a clear understanding of FDA's roles and responsibilities and how we interpret those, as well as the scientific concepts behind the expectations of the industry and our sponsors in getting products into and through the agency.

And, of course, compliance. There, we have our education and enforcement roles to ensure not only that sponsors of products understand what we want them to do, but in cases where those rules and regulations are not being adhered to, that we take appropriate action.

The next slide presents what I think are some of the forces shaping biological products in this century, and this is really driven by a number of parameters. Some of these include new discovery biomedical research. Billions of dollars are being invested through the government, predominately the National Institutes of Health. Large quantities of R&D money are being put in by the industry for the development of new products for future health and safety of the public. Well, FDA is a recipient of many of those new technologies, and the ability to have the scientific underpinning as well as the networking with the scientific community and through the use of our advisory committees to properly handle these products is very important for the agency doing the very best job.

The demand for these new products and faster

access is also paramount. Many diseases today still don't have cures or even treatments to help mitigate their effects. So the need to have the development of these new products and faster access is, we recognize, very important, but again, not at the expense of the safety of these products. And again, safety has to be looked at in the context of risk-benefit. Any medicine has a benefit and a risk factor. So as we go through both a development process as well as once we license those products, those have to be constantly assessed.

Ethical issues--new biological products raise a variety of issues, be they gene therapy, xenotransplantation, which is the use of animal tissue or replacement tissues where human tissues may not be available because of limited supply or need, and these are critical issues that go just beyond the science piece of what we do at the agency but really touch on some very basic elements of society and those things come into play accordingly.

The next slide shows the changing health care environment. The constant evaluation of where we are with medical care in this country also impacts on the availability and development of new biological products.

Globalization is key. Our world is shrinking. The ability for us to interface with the rest of the world, looking at common standards and understanding for accessing

new technology products as well as existing technology products is important, as well as standards for overseeing their safety.

Information technology, there is a boom and the agency recognizes the importance of this. Access of information into the agency as well as out of the agency is critical.

And for us at biologics, counter-bioterrorism, looking at new agents, vaccines in the event of a bio or terrorist attack has clear importance as well as other biological therapeutic products.

Our priorities for this current year are currently underway for reevaluation for next year, but I will put up the list under which we have been working over the past year and are continuing until we complete our new list. And these include, to ensure the safety and efficacy of biological products while facilitating their development and meeting the goals of the Prescription Drug User Fee Act, ensuring a strong science base supported by excellence in research that's directly targeted to the evaluation and regulation of biological products.

Next slide. To ensure the safety and public confidence in the nation's blood supply, and to facilitate the development and approval of significant vaccines, blood, and therapeutic products through review, policy formulation,

regulation development, guidance, and workshops and meetings, such as this.

The next slide shows, to improve automated systems to support review and evaluation of our products, and also to continue to develop and support a high quality diverse workforce. And I am happy to say CBER has completed the lead task that it's had on FDA modernization, so this is one that'll come off our list.

Some of our challenges, one of which is shown in the next slide, is a continuing decline in our operating budget, particularly in the areas that are not augmented by the Prescription Drug User Fee resources. We continue to look at methods in our own center to maximize our effectiveness by looking at our procedures to make sure we're getting the most out of our processes and our scientific expertise, but in this light, it still makes enormous challenges for the agency.

This is why, well, if you look at the data in the next slide, you will see that the number of products coming into the Center for Biologics are increasing. This has been a trend over the past five years. Particularly, that trend is driven by biotechnology products, and I think this is important for the agency and for the public to understand that we're in a dynamic where workload is increasing and our resources in terms of the programs are static, if not

decreasing, in some areas.

But this has not stopped us from proceeding and moving with vigilance. Some of the new approvals that we have affected deal with new heart attack medicines, medicines for bladder cancer, bone disease, hemophilia, pneumonia for babies, and new products for rheumatoid arthritis.

What are our challenges for the future? Well, there are many. Many of you who read the newspapers probably see these in there almost daily. Some of the issues regarding gene therapy and some of the challenges of approximately a year ago with the death of a young man named Jesse Gelsinger opened up areas of concern along oversight and what are we doing with human subject protection. And this opened up a broader issue in human subject protection overall, looking at the roles of our IRBs, institutional review boards that overlook clinical trials, issues of informed consents for human subjects in clinical trials. These are all important issues that not only FDA but the Department of Health and Human Services takes very seriously in moving towards finding better approaches to deal with these complex issues.

Again, using animal organs, tissues, and cells for therapy is another challenging area. Looking at the balance of access to lifesaving treatment versus risks of infectious

diseases is one that clearly we're constantly having to look at the science to balance these. The promise of new stem cell products that may be able to have replacement tissues, replacement organs from our own cells is clearly something that provides enormous promise but raises important scientific questions that need to be answered, guidance to be developed that we can go forward in the appropriate way.

We need to be vigilant with regarding emerging infectious diseases, making sure that we're doing our very best to make sure that all our products, particularly the blood supply, does not harbor new agents that can be transmitted to millions of people, similarly with tissues and other biological products which are just wonderful growth mediums for the possibility of organisms. And we need to take care in that, whether it be infectious agents or things such as BSE-like agents are very important that we look at carefully.

The human genomic project clearly is going to provide enormous potential for new products and new approaches that touch every element of the FDA, including the Center for Biologics. The opportunity for new medicines and new treatments, new diagnoses, all of which--and new discovery of medicines will clearly impact on the agency and what we get, and the opportunity to understand the science and be prepared to meet those challenges is extremely

important.

The Prescription Drug User Fee program, again, we are going to begin going into a program where we're now going to be looking at the next phase of this. It's on our agenda for the next year.

Biological product safety, again, of paramount importance both for the product and for the population taking biological products, making sure we do a good job in our surveillance and action, if necessary, with those.

I mentioned counter-bioterrorism and ethical issues earlier.

I just want to close in my last couple of slides to talk about our current outreach activities. In CBER, we have a consumer hotline. We pride ourselves on having a real person you can talk to to help you with your issues, your problems. Please take advantage of it, use it. We have a website, as well, that has a lot of important information on biological products.

Vaccines, in particular, the Vaccine Event Reporting System is a very important system for getting input. This touches on all kinds of folks. It touches on consumers that have issues with vaccines. If they think there's an event either they or their child has had with relationship to the vaccine, it should be reported. We try to do a lot of outreach. We have a little booth at the back

of the room with information on that for you today, so anybody in the audience interested, please feel free to go back there.

Fax information system, e-mail distribution list, that will send out documents, information on blood and plasma, and we try to go and be out at meetings and do a lot of outreach at exhibits to reach you.

But we want to hear today, what can we do more for you, so we're here to listen today and to learn what's important to you and really try to be responsive.

And just in closing, the last slide, again, some information on our Internet and how you can reach us at our web page, and I'll close there. Thank you.

MR. BARNETT: Thank you, Dr. Zoon. That was a lot of information in 16-and-a-half minutes. That was great.

I'll ask for a response now from Mr. Levin.

MR. LEVIN: Good morning, everyone. I've been asked to respond to Dr. Zoon's presentation, although I must admit I'm not particularly expert in biologics. But this format was an attempt to have a sort of lead respondent to try to get discussion underway, so I'll try to make my remarks as quickly as possible, and as a New Yorker, I can do it in an "under-a-15-minute" New York minute, hopefully.

So, first, some general remarks. I certainly want to thank the Commissioner, Dr. Zoon, all the other center

directors, Mark, and the FDA staff who were involved in making today's roundtable a reality. This is the first time, I've been told, that all the center directors have met with consumers and patients under one roof at one time.

The idea for this event, if my memory serves me well, began during discussions that occurred during the FDA consumer consortium meeting some time ago, and I want to especially thank the Office of Consumer Affairs for helping make today a reality. For those of you who may not know what the Consumer Coalition does, it advises the FDA on the selection of consumer representatives who sit on advisory committees, as Dr. Henney referred to earlier.

I also want to mention another organization, the Patients and Consumers Coalition, which is a group represented by a lot of people here today that's come together to work for consumer and patient issues in the FDA policy arena, and Travis Plunkett, I think, will be here later this morning, and for those of you who don't know about the coalition and are interested, you can see him or myself or Abby Meyers or anybody else, or Larry Sassick, to learn more. And that's an attempt to put our voices together to be heard with a louder voice in the process.

I'm pleased to see such a large turnout today, but I worry that the format may not permit the level of dialogue that I think we envisioned when we first started to talk

about this kind of meeting. Therefore, I respectfully suggest today should be considered as sort of a plenary session, to be followed in the not-too-distant future by breakout meetings, which would involve consumers and patient advocates and a particular center, a smaller number of discussants, perhaps, and a greater amount of time to permit more in-depth and focused discussion to go forward. And the process, and I'm glad to hear that the FDA feels the same way, this process should be fully integrated into FDA's internal planning process for now and all time.

One rationale behind today's meeting was that consumer and patient advocates as a group are probably the most supportive, although to be perfectly frank, at the same time often critical of the regulatory process administered by the FDA and supportive of the agency. But they've not traditionally been invited into the agency's planning process, or at least not at a meaningful stage of that process.

For example, I believe one glaring example is our recent experience with FDAMA, when the opportunity for public participation was a frustrating effort to make advocates' concerns heard above the roar of the legislative process. We weren't involved early on in discussions around the shape that FDAMA was taking.

And now, I think another example of a problem is

when we hear from Dr. Zoon that CBER's workload in the future is trended up and their budget is trended down. So this is another example of why there is a pressing need to involve consumers and patients in the planning process to become allies of the agency as well as critics and to help work to make things better for all of us.

The fact that consumers and patients haven't been involved seems to me to be a startling omission historically on the part of the agency, and I want to press that despite new language that's crept into the agency's dictionary, we don't view ourselves as stakeholders. I think most consumers and patients would view themselves, at minimum, as clients of the FDA. Many of us would go further and suggest that the public is the ultimate boss of the agency, which is, after all, still largely funded out of the public purse, with the notable exception of user fee income. It is the public's health and safety that the agency is statutorily charged with protecting, not that of any other interest group or sector. But as a result of not being invited into the planning process, advocates have had little or no influence in helping to shape agency policy in the past.

I would be remiss if I didn't mention that there are some pleasing signs, this roundtable today for one, that the FDA is starting to reach out, and this year's public meeting to discuss PDUFA III did have a lot of advocate

participation in talking about that important policy issue coming down the pike in 2002.

Let me turn quickly to some general responses to Dr. Zoon's presentation and try to go through some concerns that I have in regard to the responsibilities of CBER in the future. There's no question that we're experiencing the beginning of what is likely to be a rapid increase in the development and diffusion of biologic products, including gene and cell therapies, other biotech-derived treatments for injury, disease, and disability, xenotransplantation, and more. All of these are extremely complex scientifically and most have a thorny ethical component, as well.

So one concern I have is this. If the predictions are correct, how has the center built into its planning process for 2003-2004, or how will it build into its planning process, such a vastly increased workload, particularly when we hear of the budgetary constraints that CBER is going to face?

The chart that we saw of total and biotech IND/IDEs for the period fiscal year 1987 to 2000 shows in recent years a relatively sharp trendline upwards. How would you trend that out over the next five years? What's the estimate of the resources that CBER really needs to have to effectively monitor the safety and efficacy of new biologics? What plans does CBER have to attract the staff

with the scientific expertise necessary to monitor biologic products during development and in the post-marketing period?

And what about the staff needs for factoring in the ethical concerns that arise in gene therapy and xenotransplantation and other biologic-derived therapies? How is that going to be factored in? That ethical component is relatively new and it's a very large one that needs to be taken into account.

Is CBER concerned about PDUFA III? We've had a discussion of that already earlier in the year. Does CBER have any specific thoughts about the wisdom of continuing to increase the dependence of the agency on user fees rather than the traditional method of paying for a regulated agency's activities, which is out of general revenues?

You point out that one of the future challenges for both CBER and the agency is human subjects protection in the brave new world of biotech. We have read a lot about the failures of the IRB system in general, that is, that the several decades old system, I think, is generally agreed upon to be in need of repair, that it hasn't done an adequate job of protecting the research subjects enrolled in clinical trials. So again I would ask, what sort of are CBER's plans in this regard? It's one thing to say we need to monitor human subject safety in clinical trials. It's

another thing to recognize that the system we have in place needs fixing, and the question is, what is the role that CBER sees for itself in moving that process forward?

For example, the agency has taken an action in response to the death that you mentioned in a gene therapy trial. On March 7, 2000, the agency announced new initiatives to protect patients in gene therapy trials in collaboration with NCI. A gene therapy clinical trial monitoring plan appears to be very resource intensive on the part of the responsibilities of the FDA. How will this be funded? What's its priority, and will its priority, if it's high, take away from other CBER activities and responsibilities?

The center has had a blood action plan in place since July 1997, or 1987?

DR. ZOON: Ninety-seven.

MR. LEVIN: Ninety-seven, to, in the center's own words, "increase the effectiveness of its scientific and regulatory actions and to ensure greater coordination with our public health partners." The FDA has recently filed documents in U.S. District Court in Washington alleging serious violations on the part of the American Red Cross that supplies half of the nation's blood supply.

What can we do, consumers and patients, to help you create a climate that says, we don't care whether it's

the American Red Cross or who it is. There are standards, there are regulations, they're to be enforced, and we're going to enforce them. And if the American Red Cross can't get its act together, it shouldn't be in the business of supplying our nation's blood and blood products.

We can be helpful in that, because we recognize the political sensitivity with an organization like the American Red Cross and the dependency on the American Red Cross of supplying 50 percent of the nation's blood supply. I think this is something paramount as a public safety issue and we can be mobilized, I hope we would all agree, to help you create an environment that says it's okay for the FDA to enforce statute. That's not a bad thing. That's what they're there to do.

I'd like to, in talking about blood products, I'd like to refer back to the IOM report of a year ago, "To Err is Human." I was a member of the IOM committee that released that report. Now, we know that one of the categories of errors that occur in hospitals is related to blood and blood products, so I'd like to ask the question, what's CBER's response? Is CBER doing anything to address the issue of the challenge of the IOM report and the challenge that President Clinton issued in his press conference last February to reduce medical errors in this country by 50 percent by the year 2005? Has CBER

specifically looked at the kinds of errors that occur related to blood and blood products in hospitals and is there any planning to take a further look or a more in-depth look at that and then begin to suggest to the health care delivery system ways in which those errors could be reduced, and hopefully eventually eliminated?

On the agency's website--not CBER but the agency's website--is a report on the Rezulin experience. This is the first time the agency has posted such a sort of internal review of a bad experience on its website. One of the things that comes out of the report on the part of the agency is the thought that members of advisory committees as they're presently constituted may not have enough experience and expertise in risk management and risk assessment. I think that concern is going to be heightened when it comes to issues related to biologics and I just wonder what thought CBER has given to how they're going to be able to find the advisory committee expertise in risk assessment and risk management to deal with these very, very complicated products.

As mentioned earlier, and I think it's something that we talked about after the meeting on PDUFA, what about PDUFA III? What do we think about this? Does the center have a particular point of view on whether continuing to let this dependency grow on industry-provided user fees is good

or bad for its objectives? What would happen if there was no PDUFA III? We need to have some discussion of that.

Lastly, on vaccines, I think as the number of vaccines that are administered to infants continues to aggregate, I think there is growing concern about what we don't know about that aggregation in the short and long term. And also as we hear vaccines being suggested for dealing with a whole host of other kinds of problems that we haven't dealt with before, vaccines as the ultimate weapon against the spread of HIV and AIDS, vaccines to inoculate people against heart disease, vaccines to inoculate people against periodontal disease, we probably are going to see a real gold rush in terms of vaccine development to treat all kinds of things that they haven't been used for in previous years.

So the question is, again, how is CBER planning, how is it going to look down the road to this great increase in vaccine development? How is it going to be able to monitor both pre- and post-approval the safety and effectiveness of vaccines? Has CBER taken a look at how valid the Vaccine Adverse Event Reporting System is? We all know that adverse event reporting systems notoriously have under-reporting. If we're relying on that system to give us signals of problems with safety or to document known problems with safety, are we relying on a good system? Has

anybody gone back and validated that system and thought about how to increase reporting?

I'm going to stop here because I really think we want to hear from other consumers and patients who are in the audience and who were invited here today. I want to thank Dr. Zoon again for her presentation, and again, I want to emphasize that I would hope this is but the first in a number of opportunities to have this dialogue between the agency and, I think, your best friend, consumers and patients. Thank you.

MR. BARNETT: Thank you, Mr. Levin.

I noticed that Dr. Zoon was busy scribbling away during that entire presentation, which leads me to let you know that at the end of this meeting, we're going to have all the center directors come on back up here and respond to what they heard today from their responders up here and from you in the audience.

So now it's time to, in fact, open the floor for questions, and so if I see a hand--okay, one right up here.

DISCUSSION

MS. MEYERS: I have two questions, first of all for--

MR. BARNETT: Could you identify yourself?

MS. MEYERS: Abby Meyers from NORD, National Organization for Rare Disorders. This confusion about when

a biologic product goes to the FDA for approval, whether it goes through the drug division or the biologic division. For example, human growth hormone, which is really a biologic, was approved as a drug. And so it's very confusing to us because nobody really understands what the parameters are, and when a manufacturer applies for approval of a product like that, they don't know if it's going to go through biologics or drugs. Isn't there a way just to merge the drug division with the biologic division because they're really the same thing?

And the second question is, on the ethical side, this is the first time I've heard FDA talk about ethics. You don't have one bioethicist on staff, not one. So if a horrendous informed consent document comes in front of you, you really don't have any legal authority or any regulations to say, this is unacceptable. So do you intend to get bioethicists on staff?

MR. BARNETT: Okay.

DR. ZOON: Thank you, Abby. The issue you raised on product jurisdiction currently is managed through a series of inter-center agreements. Dr. Henney has asked the centers to work on those inter-center agreements, which we currently are doing.

The question of whether or not to merge different groups or different organizations is always a complex issue.

You know, there's different product responsibilities besides therapeutics and biologics, such as vaccines and blood and tissue and things of that nature. So you're looking at complex organizations and complex responsibilities, but certainly those things can be looked at and are looked at over time to look at what might be best.

But I would say that looking at having a clear set of standards that products are regulated by are very important. There shouldn't be different standards for protein molecules that have biological action that are regulated by two different centers. The standards should be the same.

And, in fact, Dr. Henney has been very supportive in fostering the interaction of the two centers to work together to develop common standards. We've been doing this routinely now for the past five years. We've worked very closely, not only on just FDA documents but also in the International Conference of Harmonization, which is a process where they're looking at standardization of elements for different products and types of products have been looked at. So a lot of work has gone on in that area and I think very successfully. There's a lot of agreement in those standards.

I think working on the inter-center agreement to have better lines of clarification is important, and as I

said, we are working on that.

With respect to ethics, right now, we don't have a bioethicist on staff. However, we do have a number of bioethicists that we have participate in our advisory committees right now, plus we interact very closely with staff at the National Institutes of Health, who do have a bioethics staff. Zeke Emmanuel is one of the persons that has a group over there that we also work with.

I think it's an important suggestion and I certainly will take that under discussion with my organization and look at whether or not it's appropriate to have somebody on staff in there or use outside experts with different experience in different ethical issues. But I think it's certainly a legitimate area and one that we should look at.

MR. BARNETT: Okay. Anyone else out here with a question? Up front?

MR. SASSICK: Larry Sassick, Public Citizens Health Research Group. Two quick questions, perhaps the Commissioner and Dr. Zoon could respond, and I suppose this shows my political naivete, but in an era of increasing new applications for biologics, and drugs, for that matter, and the other responsibilities that are being put on the agency, why over the last half-decade have we seen funding for the agency remain level or decline?

Could you tell us--maybe this is an unfair question, but could you tell us what the Congress of the United States is thinking when this is happening? There seems to be a big disconnect here. They have the responsibility for oversight of this particular agency. It looks like they're not aware of what the agency does and how important it is.

The second question is, I'd like to touch back on the issue of the Red Cross. I think the original consent decree was signed back in 1993, if I'm not mistaken. It's an inordinate length of time to be playing roulette with the blood supply. I mean, it's almost seven years. Could you tell us what you might need from a regulatory authority's standpoint to be able to deal with problems like the Red Cross and, say, other producers from being out of compliance for such an inordinate length of time? Thank you.

DR. HENNEY: I think that to have a budget session to understand how we got there would almost take a day-long briefing. I think in short form, some of the shortfalls that we have seen over time have been precipitated by a couple of things.

There was a few years back passed the Balanced Budget Act that you all know about. I think that that certainly has put some squeeze on the agency's resources as we sit before a committee that is given their allocations of

discretionary funds to spend and those discretionary funds have been decreasing over time. And many of our allocations that have been given to the agency over the last five to seven years have been in very targeted areas rather than just overall increases in the budget, which would provide the agency a bit more flexibility.

I think it's fair to say, however, within the context of the discretionary money provided to our committee in Congress--which are the agriculture committees, because we were first derived as an organization from the Department of Agriculture and our committee jurisdiction has never moved to health--that we fare reasonably well by percentage. It's just that by that percentage, it's still a low dollar amount and it's oftentimes targeted.

The other thing that has been very painful for the agency, quite frankly, has been the fact that we have not been given cost-of-living increases for five to six years. So as we need to every year still give our staff their due in terms of their increases in salary, those must come out of the other parts of our operating budget or by not hiring more staff. So you see those declines happening because of the cost-of-living increase. That has been largely because they have not been requested, and it's primarily because the kind of generous allocation that gets made to the rest of the health budget usually means that they can absorb their

cost-of-living increase.

So we've had a squeeze in two kinds of areas, the very targeted increases so we don't have much flexibility about where we can spend the money we do get, and not being given cost-of-living increases, not requested and the not provided, has really put a real damper on our ability to keep some of these things going at the level that you might expect or we would like. So there are pressure points two ways there.

Larry, I just don't think it's going to be productive for us to get into a back-and-forth on this. Those are just sort of the underlying facts, I think.

I think that the second issue, with respect to the Red Cross, I think it has been well enough known in the paper in terms of we have had the Red Cross under a consent decree for some six to seven years. We have found continued problems during the course of inspection. I think Red Cross acknowledges that and now it is really a difference of opinion in terms of a sanction that might be imposed if we see further problems, and that is the point of real debate right now. But we do believe there needs to be full compliance with the law and statutes, absolutely yes, because that is the only way we are going to absolutely assure a safe blood supply.

MR. SASSICK: Do you think you need additional

regulatory powers in a situation like this, or are they adequate right now?

DR. HENNEY: They're adequate.

MR. BARNETT: Anyone else, questions? Yes, there are two back here, one on this side and then one back here.

MS. FISHER: Barbara Loe Fisher with the National Vaccine Information Center. To what extent does CBER need or want increased resources to conduct basic science research in-house to develop a scientific base of knowledge in order to more effectively regulate the vaccine industry?

And secondly, because FDA operates theirs, which was mandated under the National Childhood Vaccine Injury Act of 1986, do you think it's within your purview to create a penalty mechanism for physicians who do not report hospitalizations, injuries, and deaths following vaccination?

MR. BARNETT: You might explain what "theirs" is just for the rest of the audience.

DR. ZOON: Yes. Thank you, Barbara, for those questions. For the audience, "theirs" is the Vaccine Adverse Event Reporting System, so everybody understands what that is.

CBER believes regulatory research for biological product safety is extremely important. There are issues with respect to not only vaccines but other biological

products that are key to not only ensuring their safety but making sure that they are continued safe even post-marketing, and I think that's an important part of our mission and clearly something we wish to do and support to the best our funding allows us to do that.

You asked, would we like more. I would have to say, sure, I think it would be helpful and appropriate. But I think we also recognize, as Dr. Henney mentioned earlier, that even with wanting more, that we also have to work with others to make sure that even in the absence of more that we try to get as much information and data to maintain the public confidence in biological products, and I think vaccines are right up there at the top. We're very eager and anxious and are continuing to do work in this area and will continue to foster that.

The second one, regarding a penalty mechanism based on the Childhood Vaccine Act, I think we would need to go back and take a look at that with our lawyers at FDA and assess that, but it's something that I'd be happy to take back and look at.

MR. BARNETT: With one eye on the clock, I'm going to go and call up the next of the center directors, Dr. David Feigal, who's Director of FDA's Center for Devices and Radiological Health, and Dr. Lee Richardson, who will be the lead respondent from the Consumer Federation of America.

Dr. Feigal?

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

DR. FEIGAL: Thank you, Mark. Let me just get started right away with the slides.

As Kathy did, I'd like to begin with the mission statement for the Center for Devices and Radiological Health. We have set two mandates, and you can see that in the mission. One is to promote and protect the health of the public by ensuring safe and effective medical devices and also safe radiological products.

It is worth pausing for a moment to mention what those are. Those, in fact, are not just medical products. It's actually all consumer products that emit radiation, whether that radiation is microwaves, such as cell phones and microwave ovens used, whether it's radios, televisions, tanning lamps, a very, very large number of consumer products. Approximately 20,000 of them per year come to the market each year in the U.S.

The next slide. Now, a vision of how we do our business is actually quite simple. We think that to ensure the health of the public, we need to be active throughout the total product life cycle and that it is not just our business but it's everybody's business. It's the manufacturer's responsibility, it's the health consumer, and it's the lay consumer's responsibility to understand how the

product life cycle for devices and radiological health products affect them.

Go to the next slide. The scope, it's very broad. The medical device industry covers things ranging from medical equipment, some of it is the kind of heavy hospital equipment like CT scanners and MRI scanners, or small things like scalpels and clamps and tubings. The implants are a particularly important group of products that we regulate, as well as diagnostic devices, including laboratory tests.

I mentioned we also have responsibility for the radiological health products, and a special law which was passed some years ago that I'll say a little bit more about in a second is our responsibilities for the quality of mammography. And then recently, we've had some increased responsibilities in the regulation of tests for the clinical laboratories.

The next slide. As Kathy showed you a little bit about her resources, let me show you ours in terms of the size of the staff. This is actually the entire history of the agency. Although FDA is a 100-year-old consumer protection agency, the Device Center is one of the newest centers and it was founded in 1976 as the merger of two programs.

The yellow part of the bar is the radiological health program and the blue part of the bar is the device

program. And one of the things you can see over the 25 or 26 years of the history of the program is that there's been a large shift in resources from the radiological health program into the device program. It's gotten to a level that concerns us because we think there are important issues, particularly as there are a larger and larger percentage of products which are being imported.

And just in the last couple of years on the radiological health side, we've intercepted night vision goggles that were going to be sold to consumers that emitted radiation, x-rays to the face, that had been used in the Russian army and would have caused cataracts in the users over time. We also recently stopped importation and got the manufacturer to correct microwave ovens that didn't properly interlock so that the microwaves didn't turn off when the oven door was open.

The little red bar up at the top is the size of the staff at FDA that runs the mammography program, although this is a program that's much larger than this. Ninety percent of the workforce for this inspectional program is actually done by the States and the red bar is our part of the staff that runs the program. And then up at the very top in the last column you see the very small Clinical Laboratories Act staff.

The next slide. I want to just say a word a

little bit about how FDA protects the consumer and kind of what are the methods that we use. Some of our responsibilities relate to making sure that the first human use of devices is safe, and we require for those types of products an IDE, an investigational device exemption, to use those products.

We're concerned about the safe experimental use during product development, and that before products are marketed for widespread use, that they be safe and effective or substantially equivalent to previously marketed devices, and that products have an adequate adverse experience evaluation by the manufacturer with reporting to us.

Another fundamental method in how we protect the consumer is by making science-based regulatory decisions. A large emphasis on that has been, and many of the arguments have been over what's the appropriate level of evidence for making a decision, for example, for something to come on the market or for a new biomaterial to be used.

Increasingly in the device world globally, there is a move towards using standards and standard approaches. I think we'll see the blend of these two approaches as we use these mechanisms.

And then finally, a very important part of consumer protection throughout the FDA is a category I would call integrity assurance. These are the areas where we deal

with fraud, where we deal with products which are manufactured badly, or where we deal with the kind of unacceptable clinical practices that occur during the evaluation of new products.

The next slide. This is another way of looking at the FDA consumer protection tools. The oldest and the earliest tools that we have, that actually go back to the turn of the last century, were the insistence that there be truth in labeling. In the 1930s, they actually gave drugs and the very first controls for devices began looking at pre-market safety controls and then pre-market effectiveness controls. We also have consumer protection tools in the Center for Devices for post-marketing studies. We actually have more authorities to require post-marketing studies than there are for drugs and biologics, and the requirements for post-marketing event reporting and conformance to standards. These are all methods that have been designed as consumer protections and work in an interlinked way.

Well, what's the role of the consumers? We hope it's going to be an expanding role. We value very much the consumers on the advisory panel members. We have consumer members on all of our advisory panels and have had that for some time. We also appreciate the focus groups that have worked with us on providing consumer and patient oriented information about devices.

We also value the reporting of device adverse experiences. There are some manufacturers who would not know about some of the problems that they have if groups of patients who have had problems with devices hadn't come forward to talk to us about those problems, either directly or through the MedWatch forms.

And consumers play an important role for us in retrieving failed devices. When we have the opportunity to look at a device, particularly an implant, that's been removed because it's failed and determined the reason for failure, we can improve those devices.

And we realize that we're dealing increasingly, in a phrase that a colleague of mine used, with information empowered consumers. The way that consumers use the net now to talk about diseases, to find out about products, to find out about studies is rapidly increasing.

The next slide. What I wanted to actually show you at this point is some of the examples of our web pages that are consumer oriented. The majority of our web pages actually contain guidances and the laws and the regulations that are more oriented to the manufacturers and to the medical professional consumers, but this is a site that illustrates some of the things we're trying to do in the future.

This is a site that presents consumer-oriented

information on LASIK eye surgery, but there is also information for the health practitioner. It's device specific. It has links to FDA labeling. One of the challenges for devices is that there is no compendium of device labels. On the drug side, you know you can always go to the Physician Drug Reference, the PDR, and look at recent copies of the approved labels. But for devices, there's no such resource. And you'll see, and actually, I'll show you other pages. Go to the next slide.

If you drill down and you want to say you've heard an advertisement and they're mentioning a specific type of laser, or you're curious to see what's been approved for the different lasers, you can actually drill down and see what has been approved. What are the types of conditions? So if you're considering a surgery and you want to have an intelligent discussion with your ophthalmologist, you actually can get a leg up by knowing exactly what the approvals are and understanding a little bit about what your visual challenges are.

You'll notice there are some hyperlinks about the approval number and date. Now, on the next slide, you'll see what happens if you click to that. These are pages that are actually available for all of our PMA products and we hope to make them available for the broader category of approvals, the 510(k) products. These actually provide the

actual documents, the labels, the approval order to the company, and the review, and if we could--I thought I needed LASIK there for a second.

[Laughter.]

DR. FEIGAL: But if we could have the next slide, please. I just drilled down and clicked on the page that takes you to our reviewer's assessment of the product for this indication. So if you're interested to say, well, how much data was there for that indication for this product, you can get down there and you can see that in this case, and I just--down at the very bottom, it says that this was a study that involved 24 surgeons, 21 centers, a cohort of 1,276 eyes. And then it'll go on in more detail. It'll describe the side effects, it'll describe the kinds of problems. This, we hope, will add to the phrase of information empowered consumer.

And then the next slide is an example. From our link, you can actually get to the manufacturer's site, and although it says up there "eye care professionals only," you can actually print out the patient information bulletin from this site.

So we think this kind of page in an area where there's many kinds of devices, and LASIK is one good example, where the consumers often want to make up their minds before they--or at least make a lot of the decision

making before they go and see an eye care professional and their source, if they don't have an objective source, is advertising and their friends and neighbors who have had the procedure.

Go to the next slide. This is back on the rad health side of the coin. This is our home page for our mammography program, and I just wanted to again show you a little bit of our outreach here. This is also a page that has both information for lay consumers and for mammography professionals.

Go to the next slide. This is what the mammography program essentially does. There was a program of voluntary inspection that was proposed when there was first some consumer activism for improving the quality of mammography, but only a fraction of the facilities actually volunteered for voluntary accreditation.

And so when we go in yearly, we check the dose, we check the equipment against a phantom that has--it's a device that simulates looking at a breast for masses and tests the ability of the device to find those. We look at the equipment. We look at the qualifications of the technologist or radiologist, the health physicist or the facility. We look at the procedure for patient complaints and we make sure that patients are getting their results on time. And we assure, as best we can, that the hospitals and

that the facilities are abiding by requirements that patients can self-refer for mammography. It's actually a requirement that HCFA has that we agree with, and it's a requirement, actually, for HCFA reimbursement that you provide those services.

Go to the next slide. This is actually a slide from the middle of a longer presentation on the history of how this program came about. It's actually a user fee program and not a very controversial one. It's a fully-funded user fee program. But the part I highlighted was that part of the reason we have this law is that there was vigorous lobbying of Congress by consumer groups who found the situation of self-policing by the mammography facilities unacceptable. There was just too much variability in the quality of the services.

The next slide. This is, again, a screen shot from a mammography page. This is a newsletter that is available in hard copy, but it's actually more convenient to get it from the web. These are just three of the different pages. Up in the corner with the beard leaning on his shoulder, there's John McCrowen [ph.], who heads our program here.

Can I have the next slide? This is a more consumer-oriented bulletin. Again, it can be printed out. It's available in hard copy, but it's on the web and it's up

to date on the web.

The next slide. So we encourage you to use our web pages. Actually, I almost don't need to say that because some of our web pages alone have 100,000 consumer downloads of booklets per month for products that are used only that often per year. And so we think there's a lot of use of this, but we hope to see it expand. We would like feedback on how to have a more effective consumer side to our web page and how to make it more effective.

You can give direct feedback to the web if you get to the website. You also can e-mail me just by saying Director@cdrh.fda.gov, and we have a consumer hotline, as well, that you can call and talk to a live body.

Let me just close a little bit on the theme of the total product life cycle and how that relates to science and how we do business. This is a diagram that encapsulates a little bit the way that products are developed, that devices are developed. They begin as prototypes. There are some pre-clinical or non-clinical studies that are done. There's clinical testing for some devices. And then manufacturing and marketing for commercial use begins. Products become eventually obsolete or removed from the market, either by market forces or less gracefully if there's a recall, and the cycle begins again as products are replaced.

And one thing that's different about devices and

drugs is that the average life expectancy of a given model of a device is only about 18 months before it's replaced by the next model of that device. So this is a rapidly spinning process that's going all the time.

Go to the next slide. When we want to protect the consumer throughout the life cycle, I think what this implies to us is that we acknowledge our responsibility for safe and effective devices from the concept to the obsolescence of the product. This is a global process, that stakeholders, consumers, the manufacturers, the public health community, all are partners.

It's inherently a science process. We intend to work to meet all of our statutory responsibilities and we intend in the center to meet our own standards for quality. We'd like to be able to pass an FDA inspection if we had to do that.

Go to the next slide. So if you step back and you look at what are some of the science that surrounds the total product life cycle, you see the kinds of challenges and the types of disciplines that we need to do our work.

At the earliest stage, at the concept stage, we need to have people that are expert in design and engineering. If we're designing an implant, for example, we have to understand biomaterials, how are they biocompatibility [sic], what are the toxicology issues for

implanted materials?

What's the mode of action? Can we develop hazards in the early testing phase that will predict how the devices have to be designed so that they won't fail?

We need the clinical sciences within the center that represent the fields of clinical trials and statistics. As manufacturing begins, we need the systems that understand how to manufacture products sterilely. There are hot topic issues in our quality systems. Reuse of single-use devices is currently one.

As the product matures and is more widely marketed, we get to rely on the sciences of analyzing events as they're reported and forensic engineering as we evaluate failed devices and problems, and risk analysis at the end of the life of a product and to help in the decision making about what to do about old products. There's actually that done on a grand scale in the last year with Y2K, which seems like a million years ago at the moment.

But when you step back and look at this, I think you'll see fundamentally that the regulation of devices is inherently a science-based activity, all throughout the life cycle of the product. Our challenge is to make science-based regulatory decisions, to have effective communications with consumers, with medical consumers, and to ensure that safe and effective medical devices are available.

That was my last slide, so let me stop.

MR. BARNETT: Thank you, Dr. Feigal.

Dr. Richardson, a little response?

MR. RICHARDSON: I think you got an excellent presentation in the sense of seeing just how many pieces there are to the puzzle, both from the point of view of the FDA doing its work and also from the point of view of the outside looking in as to what needs to be done and where decision points are and everything from first contacts with potential makers of products all the way through what could be a life of many decades for a particular product. It is an enormous undertaking.

One of the thing about devices that occurred to me, and I haven't had any of my consumer friends disagree so far, but here's tossing it to you, too, and that is there isn't really anybody who's interested in devices as such, as a generic category. What it is is a device that does this and works to help out on a particular disease or a particular infirmity, and that's why you're interested in it. If you have a bad knee, you're interested in a device for a bad knee. If you have bad ears, then you're interested in a device for ears. And if you have certain eye problems, you're interested in devices related to that.

So the normal organization of consumers is around the problem as opposed to the device, so I think that adds

to the challenge, at least in the device areas, with what limited knowledge I do have, to the center to try to deal with really a huge area of constituents who have come in many shapes, colors, and sizes in terms of their problems and issues.

One of the things about the consumer definition that we always have to keep in mind is that consumers are coming in at least two forms. Much of the presentation fairly and interestingly looked at the issues of generally informing consumers, or also being able to help consumers who have a specific question search through and find the answers. But those are really two sides of the same coin, consumer information.

The first is a whole lot easier. Here is general information about a particular kind of device or a problem. The second one is a search engine and contact people who can deal with persons who have a specific need and would like to get really authoritative information from FDA.

And approaches there would be very different. The first can be done by highly informed single individuals, even, in preparing pages on a particular issue. The rest requires an organization that functions and can get you from your first point of inquiry, whether it's through the website or a telephone call or an e-mail, to the place where the answers are. It's also much more resource-intensive,

obviously, to try to do a lot of that.

I picked up on the concept of product life cycle. It might be interesting, since my real profession is as a business professor, wearing a consumer hat--I'll leave that to you to evaluate--but product life cycle from a business point of view is getting past all this preliminary stuff, such as regulations, that we have to go through in order to get into the market. Then you get into the product life cycle. The motive is to push the process fast, keep the cost down, and then get to market, hopefully finding the customer acceptance.

The consumer point of view, I think, is we want to know that everything preliminary to the product life cycle in the industry definition of it, before it's born and becomes a reality offered by doctors or drug stores, that it has been properly evaluated, and then once it enters into the market, which, as we know, is where 275 million guinea pigs sometimes have to really further use it and test it in order to find out small problems but maybe very serious problems that affect particular groups, and it's impossible in an economic sense, perhaps, to do all of the testing in advance. There are just things you find out once you turn a particular idea that's been approved in a laboratory setting or in small-scale testing into a product that's out there being used by real people.

Part of what the problem is, of course, is real people not only find occasionally, as with drugs, very serious problems with those drugs or with devices, perhaps, as well as other products that are approved by the agency, but people don't use them as predicted, or they run into issues that are unusual.

I want to talk a little bit today about a participation I did with FDA. It happened to be driven by the fact that I'm also a patient in that area with somewhat impaired hearing. One of the issues, I have found, in talking to audiologists is that a huge number of their older patients simply have trouble operating hearing aids, forgetting about how to operate them.

I have a family experience that occurred over about 15 years where it became progressively more difficult. Meanwhile, hearing declined and the ability to manage one's two hearing aids, remembering to change the battery or knowing what's the problem or even remembering to put it on or what to do when it seems to be blocked in your ear and all kinds of other issues, these kinds of management issues need to be, or consumer management issues, I think, need to be monitored.

Are all those people who are buying and not complaining, are they really getting the use out of it, whatever it is, product or device, in particular in this

case? Are they really getting the full use out of it as you anticipated or were told by the company, or are they filing their devices in the nearest desk drawer because they're just so frustrated with it? That's when it's removable, that is.

I wanted to kind of address the process of consumer participation. I will go in and out of what groups can do versus what an individual consumer can do in the form of participating in an issue before this center. I don't want to really focus on the particulars of one company and one product. I may slip and tell you the name of the company, but I'm not trying to remake my case. I'm trying to illustrate some points. And, as you might expect, this has to do with a product related to hearing, a device.

There are 30 million people in the United States who have some kind of hearing impairment and the degree of this is, of course, measured differently by different people, but it's a large number of people and it ranges from modest to extreme. So the solutions for all these people are clearly going to be different.

What is astonishing from the trade associations, the professional health groups, is the small percentage of people who are seeking any help at all. Men, I guess, are worst of all. They just can't admit that they can't hear. And so I as in denial for, I don't know, I admit to five

years, but it might have been 15 before I really believed anybody telling me they had said something that I didn't hear.

But the point is, from a public health point of view, that maybe the biggest issue in this particular area is making people aware of solutions and dealing with it, and that's not just an FDA charge to do something about that, but it's a huge problem that doesn't seem to be particularly well addressed, but yet people who are expert in the field, like audiologists, will tell you that right off. I wish more people would come in here. It's a serious part of this problem.

But in any event, partially to try to find out how the process works and partly because I was interested in this particular kind of product, I found by accident a company that existed so far totally to introduce one product. It was an insertion that you'd have to have an operation, and also you'd have to carry something on the side of your head which really picked up the sound and transmitted it to that device in your ear. But anyway, complicated and it required an operation.

When I discovered the company's point of view, they seemed to think it was a panacea for moderately impaired consumers, and I thought, well, that's interesting. Sure, it's trouble with hearing aids, but do you really want

to go through at least one operation and perhaps two and have something inserted in your head when maybe another alternative is better? So I didn't know the answer to that, but I wanted to check into it.

I found, as I began to test the process on how to do that, that I needed a lot of help and I had been on an FDA advisory committee and I probably should be the one telling other people how to use it. I found getting to specifics about a particular procedure or process in the FDA and where it is and who can I contact, whether it's for consumer information or even technical information, wound up consuming more of my time through the whole effort than did thinking about it and trying to analyze the issues once I discovered them.

That may be inevitable to some extent, but on the other hand, maybe that's the way to focus on improving the process, is to make the consumer process simpler. I wish we had a Congress that would do that instead of saying, make the industry's process so simple and fast, but let's maybe focus on the consumer speed and simplicity.

If people get frustrated trying to use the process, that means FDA gets less input from either individuals or groups who might, if the process was faster and more efficient, be able to make a better statement and provide more consumer perspectives on a particular issue.

So that's kind of a general principle that I saw as I struggled with e-mail addresses and phone numbers and so forth trying to find the answer, and I was calling toll-free. I can imagine someone in the West trying to make all these phone calls and paying the bills as a consumer or a volunteer organization.

Another thing I realized as I did this, I was only getting in on the last short part of the cycle. This product has been in development a long time, several years, and it only surfaces for me to find out anything about it in later stages, or at least that's the way it appeared. And I'll come back to that when I tell you what the company told me about another company.

MR. BARNETT: We're running close to 15 minutes behind.

MR. RICHARDSON: So there's a need, then, for a way to tell consumers and consumer interest groups that issues are coming down the road.

I essentially got involved 30 days before product approval for the general market. That was too late to really be effective. I think many consumers and consumer groups are going to be part-time participants in the process and not follow the life of a product through that whole cycle Dr. Feigal mentioned.

So early knowledge is needed. There's a need to

get the details on the process, who to contact, related to particular issues not simply the general process followed by the agency in dealing with issues in general.

Also, I think there should be more referrals and connections to other agencies. For example, FDA and CDC and other elements within HHS are often collaborating, particularly in the life of the product, and more connections to find out where the real action is and the resources are would be helpful. Thank you very much.

MR. BARNETT: Thank you, Dr. Richardson.

Let me open the floor now to questions from the audience. We'll start over here and go around.

DISCUSSION

MS. COHEN: I thought I was going to be quiet, but I can't. My name--and some of you are already looking and knowing who it is--my name is Susan Cohen and I've been a consumer member of an advisory panel and have been reappointed.

I sit in these rooms and I think, this is not America. You talk about websites. We have 43 million Americans without any health care at all, and I'm sure most of those people don't have websites. Why doesn't the FDA do public service announcements on the media? Questions to ask your doctor when they provide medication. This idea of being wedded to a website for me is appalling because we

have too many people that have to spend money on other things. So let's be visible.

In terms of calling the FDA a consumer protection agency, you know, I spent 15 years in consumer protection. You're not a Federal Trade Commission. You have too much voluntary compliance. When you have phase four, they must comply within a year. If they promise to provide you things, they must sign a written agreement that they must provide that information within a specific period of time.

In terms of--and I think that cease and desist agreements are very scary for manufacturers and if they know they have to comply, then they might do something.

In terms of PDUFA, I need a little help. I understood that in the budget, the users' fee comes in, but the budget for the staff of the FDA had been reduced and, therefore, you weren't as effective in moving as quickly as you wanted to move, and I'm not always sure quick is that effective, and that perhaps they don't have to supply as much information as they did before.

I'd really like to have some clarification on the budget and on this PDUFA fee, and users' fees come from industry and industry has power and you have to have equal power. So if I'm wrong, I'd like to be corrected on that, please.

MR. BARNETT: We had a couple of interesting

questions here, dependence on the web as opposed to other sources of information for the public, and the situation with PDUFA. Does anyone want to--

DR. FEIGAL: Well, let me just comment a little. We use all the media. I mean, in the last month--well, yesterday, I was on Canadian public radio in an area that's also heard in Detroit on the drive-by on a live interview talking about LASIK and consumer considerations about that. In the last quarter, I've been on the Larry King Live show, which requires cable, which some people still may not have, but talking about cell phones. I was in the November issue of Glamour magazine, much to my surprise--

[Laughter.]

DR. FEIGAL: --talking about the safety of breast implants. So it's not the only media that we use.

Your point about public service announcements is well taken. We have not provided the kind of background feeds and the kinds of things that local areas could use. But it's an area--I think, historically, if you go back more than a decade, I think you'll find that the assumption was that FDA provided consumer protection by keeping the manufacturers in line and would work through the manufacturers, not directly with consumers. And I think what you're seeing is the change in that approach as we move forward, and with short presentations, it's not possible to

present all the things that we do.

But when 100,000 consumers download a consumer booklet in a month, we don't have that kind of postage. We don't have that kind of staff to even stick them in the envelopes. So the web really is also something that I think is very, very important.

Just quickly on the user fees. There are different user fee programs. PDUFA is the program in drugs and biologics that pays for approximately 50 percent of the pre-market review for new drugs and biologics, and there is nothing in the PDUFA program or FDAMA that changed the standards, that lowered the standards of the kinds of information that companies have to provide or changed the penalties for providing us misinformation. We have different authorities than the FTC, but we have some that takes manufacturers out of business in a lot quicker form, and the whole difference in rationale. The FTC's consumer protection is based on the notion of business fairness, where ours is based on public health protection. So the two are complementary, and, in fact, we have shared responsibilities between us and FTC.

The mammography program is an interesting one to ponder when you think about user fees. It's 100 percent user fee paid for, not 50 percent. It's paid for by the mammography facilities, not industry. If we did not have

it, the programs that--the same facilities, before the inspectional program, under the voluntary program, less than a third of them signed up for voluntary certification. This program is an example, I think, of where user fees work well and where we're able to do something that was never done before.

How many times do you find a service offered by a physician or a hospital that's inspected on a yearly basis, that meets standards and has a certificate that's required in the lobby and that gives us the authority to take these facilities offline? It's an unusual example. It's in a focused area, but I think it's an interesting combination of successes that would not have been possible to do if the mammography facilities had not paid for their own inspections, and they have an interest in providing quality, as well.

MR. BARNETT: Thank you. I feel like a railroad conductor, hoping the train's going to get in on time.

DR. FEIGAL: Too late for that.

MR. BARNETT: Yes, right.

[Laughter.]

MR. BARNETT: Let's just take two more and go on. We have one back here.

MR. GOACH: Yes, hi. My name is Dave Goach [ph.]. I'm with the American Society of Radiologic Technologists.

In 1981, Congress passed the Consumer Patient Radiation Health and Safety Act. This law mandates that States establish a safety net, a minimum level of education and training for radiologic technologists. These are the hands-on people performing health care radiological procedures--x-ray, CT scan, mammography.

To date, 19 years later, 15 States and D.C. have done nothing, passed no laws. We have seen at ASRT documented cases where literally individuals are flipping burgers at Wendy's one week and the next week they're exposing the general public to ionizing radiation. Despite FDA and CDRH's mandated position in protecting the public from non-beneficial and/or unnecessary exposures, it has been inactive, and, in fact, from our experience, unaware of the problem or even the existence of the '81 Act.

The CARE Act, the Consumer Assurance of Radiologic Excellence, was introduced this year and it ties a State's compliance to the '81 Act and Federal funding of Medicaid. We expect it to be reintroduced in the 107th Congress. This is not an obscure bill that ASRT is pushing. It's supported by 15 other health care organizations, including the American College of Radiology. It's endorsed by the National Coalition for Cancer Survivorship, the Cancer Research Foundation of America, and the American Cancer Society. It also has other supporters, other consumer

groups, veterans' groups.

The FDA has deemed it--

MR. BARNETT: Excuse me. I'm going to interrupt you for a moment. The ground rules were that we were going to give priority, and we have limited time, to consumers--

MR. GOACH: This is my question.

MR. BARNETT: --and so what I will ask you to do is to discuss that later, perhaps, with some of the FDA folks during the break or during the lunch hour. It's a good question.

MR. GOACH: Well, my question is directly related to the mammography point he made up, if I could just finish. It's two sentences.

MR. BARNETT: Okay. Make it a quick one.

MR. GOACH: The FDA has deemed that the quality mammography, as one of your slides points out, that technologists are qualified and certified, and we support that. I state for the record, ASRT supports MQSA. However, mammography is only eight percent of all medical imaging. My question is, can we expect FDA to take a proactive stance to ensure the quality of imaging for the other 92 percent of imaging?

DR. FEIGAL: Well, thank you for your question, and actually, thank you for your activism on this issue because it's one that actually has kind of slipped off of

many groups' radar screens. In fact, the Environmental Protection Agency, which has some responsibilities in this area, and the NRC, which also has responsibilities, have also had steady reductions in the size of their programs and staff.

One of the areas we've been proactive and are very concerned about are the increased radiation burns we're seeing associated with the use of more high-tech invasive cardiovascular procedures, the use of the stent that Mr. Cheney had a couple of weeks ago. The level of training and the design of the equipment that delivers that are all parts of things we take responsibility for.

But you are right to criticize the fact that the programs have diminished in size rather strikingly and they need repair. They need activism on our part. They need activism on your part.

MR. BARNETT: Thank you. One more.

MS. HAIRE: Doris Haire, American Foundation for Maternal and Child Health. Is there any FDA regulation that requires the makers of ultrasound equipment to provide the user with the amount of energy emitted within specific ranges of times? As you know, ultrasound is used with wide abandon in this country, even more so in other countries, but we find that many women are exposed to ultrasound hours at a time during labor.

DR. FEIGAL: One of the challenges is to give the consumer back information that's usable for them, and I think even many physicians wouldn't know what to make of the amount of energy exposure unless we find some way to quantify it. I say that just to point out how challenging the issue is. It's an issue that we've grappled with.

We have taken the stand, for example, that--they were described as boutique ultrasounds that were being set up in shopping centers and other areas where pregnant women could get a photo of their baby while they were out shopping. We took a stand that this was not an acceptable practice. It was not acceptable to have this excess exposure, even though people would say, well, what's the big deal? It's sound waves. And I think that's one of the challenges of radiological health, is that there's issues associated with each type of exposure.

MS. HAIRE: Do you agree that the long-term effects of ultrasound on human development is unknown?

DR. FEIGAL: We would agree with that. There have not been the kinds of studies that demonstrate what the upper threshold would be at a safe level.

MR. BARNETT: Okay. I'm going to call a halt here because we are running behind. We want to have enough time at the end to get these folks back up here and to respond, and so it's time now to take a break. Let's make it ten

minutes and we'll be back here at that time. Thanks.

[Recess.]

MR. BARNETT: Okay. If you'll have a seat again, we'll get started.

Our next FDA center in the tank, so to speak, is the Center for Food Safety and Applied Nutrition, Joe Levitt, the Director, and his lead respondent will be Dr. Michael Jacobson of the Center for Science in the Public Interest. So Joe, I'll turn it over to you, and again, we have a 15-minute guideline for presentations and responses.

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

MR. LEVITT: Thank you, Mark. Of course, to me, 15 minutes is about one breath.

MR. BARNETT: I know you, Joe.

[Laughter.]

MR. LEVITT: So you should have told me ten. Thank you. It's a pleasure to be here. Again, I'm Joe Levitt. I'm Director of the Center for Food Safety and Applied Nutrition of the FDA, and Mike, welcome.

MR. JACOBSON: Thank you.

MR. LEVITT: I've got my prepared presentation, but I want to respond and pull in just some of the comments and themes that came through this morning, and one is, I think, the need that I heard, really, was the need for FDA to open up as much as possible its decision making process

to provide the consumer input. And actually, that was one of the strong views that were presented to me when I took this job about three years ago, including from Michael Jacobson, and we've tried to do a number of things to respond to that.

We had a broad priority setting meeting where all, if you'll allow the term stakeholders--I heard different views on that--but people that are interested in FDA come in and tell us what they thought our priorities should be, and we utilized that and I'll talk about that and priority setting, and Mike testified and presented there.

We had two open public meetings on the whole subject of dietary supplements. You'll hear me talk more about that, and I think actually Irene Heller [ph.] from your staff was there. We had Dr. Henney and I and Sharon Smith Holston chair three public food biotechnology meetings around the country, and again, we had consumer representations at each of those panels.

We had a public meeting on the subject of dietary supplement claims dealing with the Pearson decision, and Bruce Silverglade came and spoke at that. This summer, we had, what we called a current thinking meeting on our egg safety on-farm standards that Caroline Smith DeWaal and Richard Wood, and I see Richard is on at the next panel, but was very helpful in that process.

We recently held a roundtable discussion with consumer groups and other groups separately on the subject of methyl mercury, and we've continued our priority setting process in a written fashion, and actually we went out and reread your comments from this past August in terms of priority setting for the future.

So we have tried to set a tone of open public participation, recognizing from your point of view this may sound like five things over the course of three years, and from our point of view it feels like a lot. So we do have to figure what the right balance is. But at least I want to say we clearly have made an effort, and we've also gone out to other conferences. We spoke at the annual National Food Policy Conference that's here in town. I've been a couple times to the National Consumers League on dietary supplements, and there are more things, but if I do that, I use up my 15 minutes.

So with that, I just want to use that as kind of an opening. I'm clearly very engaged. When I took this job, I will say quite bluntly I was told one of the real needs in the foods program was a stronger focus on consumers, a stronger open door policy, and I've tried to take that to heart, though obviously welcome additional input.

What I'd like to do today is a few things. Number

one, talk a little about the values we're bringing to the organization, talk a fair amount about priority setting, talk about resources--that has come up already today a couple times, talk a little bit about long-term goals.

Values--when I came, although I have worked at FDA my whole career, by now about 22 years, my previous job being in medical devices, so I enjoyed the last panel in particular, but nevertheless, when you move into a new job, people want to know kind of, who is this guy? What does he really stand for? What is he trying to bring to the job? And one way I tried to do this was to present the following values to our staff, if you could go to the next slide.

Number one is public health and safety, that we are a public health and safety agency and that ought to underline basically what we do. That's why we work here. That's what we want to accomplish.

Number two is respect, something you don't often see on one of these slides, but I think with having worked in the Commissioner's office for a decade or so, I've always been impressed with the need to hear respectfully views from many different quarters. The FDA affects virtually all aspects of citizens in this country and I've tried to bring a very respectful tone. Of course, we hope we get that in return, as well, but I put that very high on the list.

Number three is integrity. Having lived through

myself, again, in a previous life, the generic drug episode at FDA, if FDA loses its integrity and its credibility, we've lost our essence of what we bring to the table. And so we try to put integrity, again, very much front and center and uphold those high standards. I know all my colleagues at FDA share that.

Number four is dedication. If you say nothing about FDA employees, you will say they are dedicated--we are dedicated. People work long hours. People sacrifice higher-paying jobs and we want to be sure that that same dedication is there day in and day out.

But it's not just a dedication to working hard, it's a dedication to excellence, to excellence in science, to excellence in a regulatory policy setting, to excellence in communication.

And you put all those together, you see the first five letters down spell out PRIDE. We try to instill a sense of pride within the organization, within the program, and I have gotten since then, happily, a lot of feedback. You walk in our building, you'll still see signs like this three years later as part of our culture.

MR. BARNETT: Did the acronym communication first and then the words, or the words and then the acronym? That's on my time, not yours.

[Laughter.]

MR. LEVITT: Well, it's a little of both. I have found when you put together something like that, you need an acronym or you will get one whether you wanted one or not, and so as long as you're doing it, you can try to put things in a little different order. But I was happy the way that came out.

Priorities--when I came, it was very clear--at the first priority setting, it was interesting. We had a lot of people present. The headline of the trade press the next week was, "Everything CFSAN Does Should be a High Priority, Stakeholders Tell Levitt," and, of course, we kind of expected that.

But nevertheless, as the meeting went on that day, I pressed one of the speakers that I felt I knew well enough to do this and said, look, give me a break. You know, you're telling me we have to do everything. And he said, look, it's my job as an advocate to tell you what I think you need to do, and that's going to be what my folks want. It's your job to set priorities and it's our job to live with that, but to hold you to them. And I said, that's not a bad deal. I can live with that deal.

And so that's what we did. We went and we set up through each year, and I've got my hand-held props, what we refer to as a yellow book, which in my building is known as the bible, and this sets out what we are committing to do

each year. The first year, we had our process and we asked the first fundamental question as we looked across the program and asked, where do we do the most good for consumers? That's what I asked not just for the consumers, that's what I asked the industry, that's what I asked the health professionals, that's what I asked our staff. That is why we're here. Where do we do the most good for consumers, and we've tried to lay that out.

Unfortunately, the needs are so vast that the list's a little bit half-empty, half-full. Yes, I like what's on the list, but I like all the other things, too. And so what we do to accommodate that a little bit, we have our so-called "A" list and the "A" list are the things that we are dedicated to accomplishing and bringing to fruition that year. And the "B" list are additional areas that we think are important, but either they're ongoing or we know they're early enough in development they're not going to be finished, but we want to give prominence to and show that we do see them as important and there will be time working on it. So we have developed those.

And then at the end of the year, we come out with our report card. Actually, that says 2000. Last year, we came up with our first report card for 1999 where we showed we accomplished nearly 90 percent of what we set out on our "A" list. Also interestingly, virtually nothing on the "B"

list, but to me, that was okay. That was what we wanted to do. We wanted to focus on what we thought was most important.

For this year, we converted from a 12-month year to a nine-month year in order to get on the fiscal calendar. You know, I began in the winter and so I thought calendar year was really neat. But as I got into it, I became convinced that so much works on the Federal budget cycle, we ought to be on the fiscal year. So we said, all right, since this is a nine-month cycle here, three-quarters of the year, our goal will be to accomplish three-quarters of what we set out to do, and indeed, that's what we were able to do.

I've got a chart here, which you can't read and I know you can't read it, but each one of these lines adds up to 84 of the "A" list goals here that we accomplished, and an additional 24 of what we call substantial progress made will be carried over into next year, and that was 78 percent, so we did meet the goal that we set out for ourselves and the success is really across the board.

There are four main categories. Number one is food safety. I think those involved in food safety know that it is of paramount interest. In the back, I see "FDA Reminds You to Fight Bac" as one of our slogans of the program, but we have set out together with other Federal

agencies and with State and local counterparts a true farm-to-table program to control all the way back to production and all the way through to consumption.

We have through that program devised additional preventive systems for the industry through what's called HACCP, Hazard Analysis Critical Control Points, beginning in seafood, trying to expand into juice, piloting in other areas. We have our good agricultural practices. We've just published a regulation just this past week on egg safety for refrigeration and for safe handling instruction for consumers, again thinking of the consumers.

I think what is most important here, because I would spend more than 15 minutes just on this one topic, is that if you think farm-to-table, or from production to consumption, FDA has traditionally spent time at neither end. FDA has spent most of the time at the middle at the food processors. But as we're looking at bacterial contamination, pathogens in the environment, they don't just go to the manufacturing facilities. They're everywhere. And what we've found is where the germs are, we need to be. We need to have a presence.

That means we have to go back earlier to the farm, to the production, where I have to say we're not all that welcome sometimes, where we had to devise strategies to make us welcome, and all the way through the consumer. If there

are things consumers can do to make food safe, keep food safe, we want the emphasis there, too. That's not to shift the weight. We want the weight to be applied everywhere, if you will. Dave Feigal had a nice slide about it's everybody's business. In food safety, we clearly feel that it's everybody's business from farm to table and have a very extensive program there.

Most recently, in this year's report, you'll see a focus, both an increase in inspections, but even more important than the increase is a focus on those facilities that produce food we consider to be at high risk of microbial contamination. And so we have increased those number of inspections.

We have also increased vigilance in a number of ways on imports--more work at the border, more inspections overseas, more education overseas. We import a lot of fresh fruits and vegetables from around the world and we have taken, if you will, our food safety program on the road. We have gone down to Mexico, down to South America, most recently down to New Zealand and are moving next year over to the other part of the globe, to Asia and to Europe, so that that is brought to bear. We find importers are really interested because they want to be able to import in this country. We want to be sure there's the same level of protection.

Food additives--we were able to receive some additional funds on food additives and we have both a new program underway for what we call the indirect additives, something in a plastic that might migrate into the water or from the packaging, but also for direct food additives. We want to be very clear that this is, and somebody mentioned this earlier, this is not an industry service program. We have a job to do, which is an independent review of the data, and we try to instill in all our reviewers that we want your best advice on what the review ought to be, and we give equal, if you will, kudos whether they say yes or whether they say no. What we care about is, is it scientific? Is it thorough? Is it thoughtful? Is it according to the standards that we put out?

Dietary supplements--very important, very much an emerging area, a very challenging area. We spent about a year a year ago going through and developing what we call our dietary supplement strategic plan, which lays out all that has to be done under DSHEA, which was passed in 1994. And what I say is, if there was, in hindsight, being given this law, and I won't comment on the passage of the law--Mike may want to do that--but since we have this law and it's the law of the land, since it is not a pre-market law, in other words, products don't come to us before marketing like they do for drugs or many devices, things go to market

and we police the marketplace and it's a post-marketing law. Because of that, Congress didn't think in terms of FDA needing funds or people to do that, and yet most of our center, just talking about food safety, almost all food safety is a post-marketing program.

So what we've done is we've said, all right, a post-marketing program is still a regulatory program. This is what it takes. You need safety, you need labeling, you need enforcement, you need to set your boundaries, you need your science base, you need your outreach. We've laid it all out in our dietary supplement plan and the Congressional committee in this year's report asks us to say, all right, you've got your plan. What will it take to fund it properly? And so we're busily finishing that report so we can get that to the Congress and say what our needs are there.

Finally, biotechnology. It is amazing how this issue really emerged over the last year. I reference the public meetings the Commissioner and I and Sharon Holston chaired and I think those meetings were not only helpful in the general sense but somewhat sobering, because what we heard at that meeting is consumers are really looking to FDA to, what I call do the public's bidding and not have any perception that we're somehow doing the industry's bidding. That was, I think, a strong message. We wanted to be sure

that there is high confidence. We believe in it. We believe the science is there. But we are strengthening our programs in a number of ways to try and respond to that and be sure that we are properly assuring consumer confidence and having our programs both be strong and be viewed as strong.

In terms of next year, we'll be coming out with these in a few weeks, but I think primarily we will, number one, try to finish unfinished business. Number two, project the importance of continuity of major programs. Everything I just said you'll see carrying through. There will be more to do on food safety and more on food additives, much more in dietary supplements, biotechnology, and so forth, and I think even as we change administrations, having worked in FDA through a number of changes of administration, a lot of these base programs, I think, continuity is very important to project, and that, indeed, will be the reality.

And finally, I would just note that our center is getting ready to move locations. We have a new building that is being built out in College Park right by the Metro stop, a mile from the campus, which will help with our collaboration with the University of Maryland, but just the act of moving takes time and work. We've been in our building for 40 years. Nobody has thrown out a scrap of paper in that time. We are moving both offices and

laboratories, which has not been done, and so it is going to be a big chunk of our time and we're trying to work that into our planning.

I'm sure I'm behind, Mark. I'm going to try to--

MR. BARNETT: Yes. I was going to just remind you, you're just about--

MR. LEVITT: I'm going to do this real fast, faster than it deserves, but I can do it fast.

The first slide shows when I took this job in 1998, so there's going to be an update. What I saw from 1978 was basically a reduction of 20 percent, and that was a reduction of 20 percent, this is the people that work in CFSAN. Even with an increase for largely seafood, a little bit for imports, a little bit for nutrition labeling, but this was largely the seafood positions that came in there, but nevertheless, even with that, we have a net decrease of 20 percent. That's why priority setting was so important.

The next slide, though, shows that if you take out those targeted areas, it's not a 20 percent, it's a 33 percent reduction, and most people in the program were not working in seafood and were not working in imports and that's the world they saw. They also saw a program where most people had worked there all those 20 years and so they know Joe left, Mary left, Susan left, Jack left, and they're left. And as you can see, there's a certain demoralization

that comes with that.

Now, in the last three years, I was lucky. I took the job just after the first set of new resources came in 1998. It takes about a year before you see them really come up, but you see they've gone up to 851 last year. I just looked at the new numbers yesterday. For this year, we'll be up around 900. So we will have made up half of that gap in those three years, and that's good. Consumers and CSPI in particular have been very vocal and persistent in meeting with members of Congress and explaining why those food safety funds are so critical.

But, there's this part two of the story, which is the next slide. Again, if you take away the food safety resources, and even all of these were pathogen food safety, so that still doesn't include and would include here--pesticides would be included in here and a lot of other areas--it just keeps going down, because, as Dr. Henney said, if we don't get our cost-of-living increase, which we haven't for seven or eight years, and there's a five percent increase, we'll say, that means if we could pay 20 people last year, we can only pay 19 this year. And so even though we need more people, we need people to leave to pay for the people that are here.

If that doesn't sound--I'll let you put your own characterization on it, but that's the world we live in. We

have had to live with a world that is going down, and when you see that sharp decline there, that really is what other centers in FDA also feel as a result of when we stopped getting--that's when we stopped getting our cost-of-living. So that's where we would have been if we hadn't gotten the new funding. But it also means if there isn't something done, you can see it goes up. It can go down again quicker than you realize. So that is, if you will, a resource update.

When you look at the long term--I can do this in one second--we have, if you will, felt we've gotten through a lot of short-term issues. We have things like food safety, dietary supplements they're trying to get on a longer-term track, but if you think globally, we have gotten together the center and dedicated ourselves to a three-point program, what we feel is building a truly world class organization, and there's three parts to it.

Number one is we need a strong science base for informed public health decision making, and I think historically we've done pretty well at that, although if there are gaps, we need to plug those and reinforce.

Number two, we need to have the capacity to implement those decisions in a timely way, and if there's an area we've fallen down, that's it, and you know that, and there's a long list. As supportive as consumers have been,

they've also been quite critical of time it takes and so forth, and I understand that. And so we have this in terms of capacity building. That is really the most important thing in terms of follow-through.

And number three, to have a culture shift, what we call towards a culture of accountability, cooperation, and respect. We want to be accountable, but we feel we can do it in a cooperative way and a way that is mutually respectful.

And you put that all together, we have declared this a new day at CFSAN. We hope you are feeling some of that out in the consumer community. Thank you.

MR. BARNETT: Thank you, Joe.

Dr. Jacobson?

MR. JACOBSON: Thank you, Mark. Good talk, Joe, and very nice to see you, Commissioner Henney. Thank you very much for holding this meeting and inviting CSPI to participate.

I want to focus on two general areas. One is the resources at CFSAN, following up on your slides, and then discuss what we think is inadequate attentiveness to a variety of specific consumer concerns.

Over the past quarter century, the complexity of America's food system has increased greatly. Thousands more foods are on the market. More and more foods are imported

from around the world. Dietary supplements and functional foods have become the rage. And genetically engineered products have entered the marketplace. Moreover, new laws such as NLEA and DSHEA have given the FDA new responsibilities.

Unfortunately, as you explained so clearly, CFSAN's staffing has not increased along with the increased challenges. Indeed, the staffing has actually declined by that seven percent over the last 22 years.

According to Mr. Levitt, CFSAN's staffing--that decline is incredible considering all the changes that have happened, and I think it's scandalous. It endangers the public's health and welfare. Plainly speaking, inadequate funding means more contaminated food and dishonest labels, fewer analyses and less research, slower product reviews and more unsafe or untested products.

Without adequate resources, CFSAN simply cannot do its job. The FDA's overriding priority regarding CFSAN should be to have its overall budget and staff for both headquarters and field operations, the inspectors, at least doubled over the next four years--at least doubled over the next four years. Let me add a few more details.

The FDA is responsible for inspecting over 57,000 domestic food establishments and millions of shipments of imported foods. One indication of a problem is that the FDA

analyzed one-fourth fewer domestic food samples in fiscal year 1999 than it did in fiscal year 1996, a 25 percent reduction in those analyses.

When the President's food safety initiative was first developed, FDA inspectors visited food plants on average once every ten years. Unfortunately, it appears that following nearly four years of funding increases under the food safety initiative, things don't appear to be a whole lot better today. In fiscal years 1998, 1999, and 2000, Congress appropriated approximately $37 million in new money to fund inspections. While that money should have been enough to hire more than 350 new inspectors, FDA staffers familiar with this issue have told us that the inspection staff has not increased by nearly that much. One wonders where all the money went, and from what you say about COLAs, maybe a lot of the money went to COLAs.

Now let me turn to some of the specific issues about which CSPI has been concerned. CFSAN is a great believer in HACCP systems, but its seafood HACCP program has serious problems. For instance, 30 percent of seafood plants have poor HACCP systems and another 46 percent have no plans at all. By FDA's own estimate, in 1999, only 54 percent of all seafood firms were in compliance with the HACCP program, but that includes the 30 percent of firms that have been exempted from the program entirely.

Unlike USDA's meat and poultry HACCP regulations, there are no pathogen reduction standards and microbial testing, which together provide a system check of the quality of the HACCP plans. In addition, while seafood is one of the most hazardous foods that the FDA regulates, seafood plants are visited by FDA only once every one or two years as compared to the continual inspection of meat and poultry at USDA.

Although FDA published a proposal for HACCP in all food plants, industry opposition thwarted the proposal. Now the agency is using a piecemeal approach for HACCP implementation, an approach that will take many years, if not decades, to implement and will never really work without pathogen reduction standards, microbial testing, and frequent unannounced inspections.

FDA needs to rethink its approach to food safety regulation. In addition, we urge the agency to seriously consider the need for comprehensive statutory reforms to its food safety mandate.

Switching subjects now, a recent NAS report concluded that mercury-contaminated fish potentially harms as many as 60,000 infants and children every year. Yet, the FDA has downgraded to its "B" priority list of "we won't do it this year" the development of a better mercury in fish standard. That, unfortunately, is standard operating

procedure for CFSAN, which long has failed to provide adequate protection to at-risk consumers, in this case, women and children. We urge CFSAN to act now to set and enforce an action level for methyl mercury in fish that is consistent with the NAS's findings.

Another food safety issue is shellfish. Every year, shellfish contaminated with vibrio vulnificus bacteria kill one to two dozen people. Another shellfish hazard, vibrio parahaemolyticus, has caused outbreaks sickening nearly 700 people since 1997. For years, CFSAN has tacitly accepted those deaths and illnesses by not requiring pasteurization or other processes to ensure that shellfish harvested from warm waters in summer months, which carry a near certainty of contamination, to ensure that they're safe.

In 1999, the FDA solicited comments on our petition for a zero tolerance for vibrio vulnificus in shellfish but has not taken any further action. Meanwhile, more people are dying.

You mentioned genetically modified foods, and those obviously pose new challenges. CFSAN may institute a mandatory pre-market review, but we fear that that will be an opaque, not transparent, process and will not provide for formal approvals. That plan will provide more fuel for biotech critics and will not maximize consumer confidence.

The FDA either should establish a mandatory transparent approval process, or if it believes it doesn't have the statutory authority to do so, call on Congress to provide that authority. Senator Durbin and Congressman Kucinich have introduced sensible bills that would give the agency that authority.

Food additives, too, raise health concerns. CSPI has filed petitions concerning the approval or labeling of the carcinogen potassium bromate, the stimulant drug caffeine, the allergenic coloring called carmine, diarrhea-inducing sorbitol, and other additives, but CFSAN has not acted on any of those and many other petitions.

In addition, in the last few years, unapproved ingredients, including herbs, have been added to so-called functional foods. CFSAN has failed to really go after that problem and nip it in the bud, although it's taken some actions.

While foodborne illnesses, GMOs, and food additives are controversial, the biggest cause of disease and premature death related to our food supply is the food itself, all too often loaded with fat, sodium, and refined sugars. The nutrition label may be the FDA's best and only means of helping consumers choose more healthful foods.

We applaud the FDA for moving, though slowly, to add trans-fat to the nutrition fats label, a change that

could save thousands of lives a year, and we hope that that will come out in this fiscal year, if not the next month or two.

Over the past 17 years, per capita consumption of refined sugars has increased by 30 percent. That's probably the single biggest adverse change in our diet and has probably contributed to soaring increases in obesity and also increases in diabetes. Clear labeling, including the listing of percentages of a daily value, could inform people about the added sugars content of foods and help people eat less, as the dietary guidelines for Americans recommends.

Health groups like the American Public Health Association, many nutrition experts, and even the U.S. Department of Agriculture have endorsed the labeling of added sugars. However, makers of junk foods have mobilized massive opposition. We hope that the FDA will not succumb to industry pressure and instead will help beleaguered consumers.

We're also concerned about other parts of the label. The FDA has long failed to vigorously enforce the misbranding section of the law. Exceptions abound. You see them every time you go to the supermarket. Companies lead people to think that certain products are made of whole wheat when they're not. Other foods are labeled to exaggerate their fruit content. Such tricks cheat people

and make it difficult to choose a healthy diet, and they also hurt honest companies. It's high time that CFSAN devoted adequate resources to preventing those kinds of unhealthful, costly deceptions.

To summarize, CFSAN, notwithstanding the many things it does well, is not a sufficiently aggressive protector of consumers. It should be CFSAN, not a small nonprofit group, that discovers Cry9C from the BT StarLink corn contamination in foods and solves the problem. It should be CFSAN, not a consumer group, that identifies dishonest labels and unsafe ingredients and gets the products off the shelves.

I urge CFSAN to do everything it can to promote the public health, despite sometimes fierce opposition from industry and Congress. The FDA must fight for a doubling of its food budget over the next four years and CSPI and other consumer groups will do everything we can to help you from the outside.

Thank you again for inviting me to participate.

MR. BARNETT: Thank you, Dr. Jacobson.

Let's open the floor for some questions. Go ahead.

DISCUSSION

MR. SAPONE: My name is Sean Sapone with Childbirth and Family Development. I have a question for

Dr. Levitt, although I'd appreciate Dr. Jacobson's response, perhaps, as well. The use of antibiotics in agriculture for livestock is becoming a growing concern. What do you anticipate the future response of CFSAN to be?

MR. LEVITT: Can I just pause and say, if you can hold that for the next panel, I think they will be more appropriately able to answer that.

MR. BARNETT: Okay. Yes, right here. Right up front here.

MR. DRUKER: Steven Druker with the Alliance for Bio-Integrity. I find it hard to believe that FDA continues to claim that genetically engineered foods can all be presumed generally recognized as safe in light of the fact that it knows full well that there is serious scientific dispute today, that the District Court has acknowledged that in the Alliance for Bio-Integrity, Center for Food Safety lawsuit we have shown significant disagreement among scientific experts and the fact is that you were informed, Mr. Levitt, by myself and many of our scientists' plaintiffs during those public hearings that you're boasting about about the extent of scientific concern, independent scientists who are not funded by the biotech industry, and yet the sole legal basis for these foods remaining on the market is the claim of the FDA that there is an overwhelming consensus among science that they are safe.

That is a false claim, and although the court upheld you on the narrowest of technical grounds, the court, because it said it would not in this lawsuit consider evidence beyond May of 1992--and by the way, that is probably going to be reversed on appeal--but you have these foods on the market because of what you call a rebuttable presumption they are GRAS, that they are generally recognized as safe.

If you will not look at evidence beyond May of 1992, it's not a rebuttable presumption. If you want to be responsible, if you want to earn respect for having integrity, then you're going to have to earn it, and the food supply is now being exposed to foods that many experts say could be very dangerous and you know that. If you continue to make this claim and do not regulate them as containing new food additives, then there is something grievously wrong with your approach and history will judge you very harshly because of it.

MR. LEVITT: I think the way I want to respond to that is, as was pointed out, this is an issue that has been subject to litigation. The District Court did rule in FDA's favor on virtually every point before it. If that is appealed, then we'll deal with it, obviously, at the next level. We'll see what comes out there. But that position that we've held, as I said, has been upheld in court.

I think it is important from our scientists' point of view, we do very much, as I've said, stand behind the safety of these products. We do have a new proposed regulation coming out to strengthen the review program. I would expect you to be commenting on that when it comes out. But it is designed to both strengthen the program and provide increased transparency to the process, and so I guess I would urge us to let that process continue and to try and make advances where we can.

MR. BARNETT: Dr. Jacobson, did you want to comment?

MR. JACOBSON: I wanted to ask you, Joe, the FDA has said that it's going to come out with a proposal this fall. Fall ends in a week. When do you expect it to come out and might this regulation be delayed by a change in administration?

MR. LEVITT: I am still hopeful that it will be coming out this administration. I'm not in charge of this administration, but that's my anticipation.

MR. BARNETT: Okay. Another question back here?

MR. MENDELSON: This is a similar follow-up. My name is Joe Mendelson. I'm with the Center for Food Safety, a nonprofit organization. I was curious on your priorities to still continue, you mentioned two citizens' petitions. Dr. Jacobson just mentioned one, as well.

Back in March of this year, our organization, along with 54 other organizations, many of whom testified at the public hearing, submitted a petition outlining proposals what we think would be inclusive of a good regulatory system for genetically engineered foods and I was wondering if you could comment on whether that's a priority to respond to that, as well, or whether you think that this new proposal is going to be a response to the petition and what type of priority you are giving this citizens' petition. Thanks.

MR. BARNETT: Thank you.

MR. LEVITT: We do have the citizen petition. We have reviewed it. We do think that our proposal is, in part, responsive to what you're getting at and we would be looking for your comments during the comment period to it.

MR. BARNETT: Okay. Let's go one more. Back here?

MS. HOCHANADEL: Thank you. My name's Deborah Hochanadel. I'm with the Massachusetts Breast Cancer Coalition, and today I'm also speaking with the voices of several other organizations that are also consumer health groups--Boston Women's Health Book Collective, Breast Cancer Action of California, Breast Cancer Action of Montreal, Center for Medical Consumer, DES Action, National Women's Health Network, Women's Community Cancer Project, Working Group on Women and Health Protection. We just are speaking

with one voice. That's why I had to mention all of our groups.

We believe strongly that the FDA has a role to play in the genetically modified food debate. Because we represent women who do most of the food buying and who are most likely to be responsible for what children eat, we have a strong interest in the safety of food supply. We urge the FDA to exercise its authority to assure that genetically modified foods reach the marketplace only when they are proven to be safe for all over an appropriately extended period of time.

It's tragic, but true, that too much of the recent history of public health is the story of uncontrolled experiments on human health. First, we began widespread civilian use of chemicals developed for wartime without first testing their effects on human health. Next, we experienced and continue to experience increased reliance on pesticides, many of which are known or suspected to cause cancer, among other diseases.

Now, in addition to these existing exposures, we're being inundated with genetically engineered foods, even though the long-term human health effects are unknown. The burden of proving that genetically engineered foods are safe should fall squarely on the companies that are marketing these foods. It should not be up to consumers to

prove they're harmful. Genetically engineered foods have not been thoroughly tested for their effects on human health.

To allow these foods to be marketed makes us once again guinea pigs in vast uncontrolled experiments. We will be guinea pigs no longer. Please be aware of this. The interest of the public's health must be put before private profit. Thank you.

MR. BARNETT: Thank you. Do you want to respond, Joe?

MR. LEVITT: Well, again, really, all three speakers, all three questions have spoken to the same issue of biotechnology. I think this reflects the broad public interest there is in this issue. In my time at the FDA, I can't remember having public meetings around the country with so many people. The one here filled a room at least twice this size, maybe three times this size.

There was a lot of public interest in it and we are both trying to listen, trying to exercise our best scientific judgment and experience in being sure that whatever we're doing as next steps provides for a round of public participation, both in our proposed regulation, which I said we hope will be coming out on the review process, as well as a guidance document we're putting out with respect to labeling. And I think, again, by providing a period for

public participation is, as I said, an important part of the process.

MR. BARNETT: Again, I'm trying to balance the need to get as many questions as I can from you with the need to have enough time at the end of the day for these center directors to come back and respond to their respondents, and so with that in mind, I think we'll go with one more short one and then go on to the next. Here, okay. Identify yourself and please try to make it brief.

MS. SMITH: Thank you. I'm Fran Smith with Consumer Alert, and I've been interested in this discussion, but also earlier Commissioner Henney had mentioned that everything is to be science-based from the FDA's standpoint, and also, I think she referred to the fact that there is a problem in being too risk averse. I think in the biotechnology area, I think there is a danger of a retreat from science and danger of being too risk averse, and we usually, from a consumer standpoint, we always look at the risk of innovation. There always is a risk of new technology. But there always is a risk of stagnation.

I'm very concerned when I see the FDA perhaps listening too much to people who would look for zero risk in every aspect of our lives. For instance, biotechnology can reduce the risks of micatoxins in agricultural crops, the most carcinogenic substances probably that can occur

naturally, and yet we have no one talking about some of the risks that biotechnology can alleviate.

So as a consumer group, I would urge the FDA not to look at only one side of the risk equation but to--I know you phrase it risk versus benefit, but I think you really have to look at risk versus risk and the risk of unintended consequences from a zero-risk approach to regulation.

MR. BARNETT: Thank you. Response?

MR. JACOBSON: Well, I just wanted to interject, the questioner identified herself as Consumer Alert, a consumer group. Could you tell the audience how much support you get from industry?

MS. SMITH: Right now, we get very little support from industry. We have most of our money from individual donors and foundation grants, and I think any food-related industry right now is probably about $10,000 or less. I resent the ad hominem attack, Mr. Jacobson. You have worked with me in the past and you know that we take consistent, credible, principled, pro-market, not pro-business, positions, and I think--

MR. JACOBSON: I wasn't casting any aspersions.

MS. SMITH: I'm sorry, Mr. Jacobson--

MR. JACOBSON: In the interest of transparency, it's useful to know.

MS. SMITH: That is transparency. That is

transparency.

MR. BARNETT: We asked the question and it was answered. Okay. Joe, any response to that?

MR. LEVITT: Again, I think the only way I would respond to that in a way is the same as to the prior response, which is we try to take, I'll say a balanced approach in terms of looking at both what's ahead but also what's on both sides. We need to look at what we know. We need to know that we're not always going to know everything. When do we know enough to go forward? When is it not enough? These are judgment issues. These are scientific judgment issues which we do all the time. Often, they are subject to public criticism or different views from that and that, I think, is simply part of the process.

What's important, I think, is that from an FDA point of view, that we strive, too, as Dr. Henney said, as I've tried to reinforce, be science based, think first and foremost in terms of public health and safety, recognize there will be people out there with different points of view, have a public participation loop to be sure we're listening to everybody, and then finally, adopt a position that we feel we can defend, that we believe in, and stand behind that, and that's how I think we provide assurance to the public at large that the FDA is doing the right thing.

MR. BARNETT: Thank you, Joe, and that will

complete this aspect.

I will now call up the next center, which is the Center for Veterinary Medicine. Dr. Stephen Sundlof is Director and his responder will be Dr. Richard Wood of the Food Animal Concerns Trust. By the way, Dr. Henney will be back. She had another meeting, but she will return shortly.

If everybody will regain a seat, we'll begin. Dr. Sundlof?

CENTER FOR VETERINARY MEDICINE

DR. SUNDLOF: Thank you. Thank you, Mark, and I'd like to thank my counterpart, Richard Wood.

DR. WOOD: Thank you.

DR. SUNDLOF: I appreciate the effort to get here and to talk with us today about some of the issues that CVM is dealing with, and Richard has been one of our consumer representatives on our advisory committee and has done an outstanding job and it's really nice to be able to work with somebody like Richard.

We're the Center for Veterinary Medicine, maybe the least recognized center of the other four that you'll hear about today, and it's kind of interesting to talk about what CVM's mission is, and that is we have really a dual mission. It's to protect public health, and also we feel a strong commitment for providing for the animal health, as well.

We're much like several of the different centers. We have combined responsibilities, even though we're one of the smallest centers in the agency. Like drugs, we have to review and make judgments on the safety and efficacy of drugs, just as the Center for Drug Evaluation and Research does. In addition, we're very much like the Center for Food Safety and Applied Nutrition in that we make food safety decisions, and we even do a little bit of device work, although we don't do any pre-market device work. So we are like at least three other centers and we're unlike CBER, biologics, in that the U.S. Department of Agriculture deals with the vaccine issues.

But again, our mission is twofold. Healthy animals will provide for wholesome food. We're concerned about such things as drug residues, and the subject that I'll talk about most extensively today will be in the area of antimicrobial resistance, which a question was just asked of the last panel.

We're also responsible for making sure that the products that we approve for animals are safe and effective and for protecting animal health. We have a number of veterinarians that work at CVM, as you might guess, and they all have a very strong commitment to maintaining animal health, but we always put public health above animal health.

We had a law that was actually enacted a year

before FDAMA, the Food and Drug Administration Modernization Act, and it's called the Drug Availability Act, and it was our reform act. It did many of the same things for the Center for Veterinary Medicine that FDAMA did for drugs. It gave us some additional flexibility to speed up the process. But one area that it did not touch was the public protection, the food safety issues. That Act specifically preserved the existing food safety provisions that we had been dealing with over the past.

The process that we use is still very deliberate. The drug must be safe, and when we talk about safety for veterinary drugs, we're talking about safety to the animal, just like a human drug must be safe to patients; safe for the public who consumes food derived from those animals; and they must also be safe for the environment. They also must be effective, just as human drugs must be effective.

The applications are reviewed on the basis and such things such as economic requirements are not factored into any of our decisions, even though we require many, and, in fact, most of the same stringent factors that FDA does for human drugs. The economics of the animal drug industry are much, much different. There's no third-party payers. They are generally fair low-profit margin compared to their human counterparts. So there's a different economic dynamic in the animal drug sector. Nevertheless, we do not take

those issues into account when we make decisions on whether or not to approve an animal drug.

The area I'd like to spend a lot of time talking about, because it is our top priority area, and that is antimicrobial resistance. About six years ago, we decided that we really had to take this issue more seriously in terms of how we regulate these products to ensure that the use of the drugs in animals does not put the public at any undue risk. So we've taken that very seriously. It demanded a tremendous amount of resources in order to put together the kind of program that we thought would be adequately protective of the public health.

Fortunately, at the time that we were struggling to put our programs into place, the President's food safety initiative came along and we were able to benefit substantially from that in building the program that I'm going to be talking about today.

One of the first things that we recognized is that we needed a new regulatory process by which to evaluate these drugs before they were approved for use in animals, and that document was published in 1999. It's called the framework document. It has a much longer name, but most people refer to it as the framework document. It is available on our website for anybody that wants us to take a look at it. And since that time, we've been working on

various pieces of that to try and implement them so that we can build the proper regulatory structure to be able to evaluate drugs on the basis of their ability to cause antimicrobial resistance.

We think that having open discussions on this has been very beneficial. We've had, in addition to open public advisory committee meetings, we've had three open public meetings since October of 1999. We had a general meeting on antimicrobial resistance, followed in December by a draft risk assessment that we published on campylobacter and the use of flouoroquinolones in poultry. In February 2000, of this year, we held another public meeting to look at such things as the amount of pathogens that the animals carry with them and how this would impact our ability to approve a drug.

We will have our next meeting next month. It will be probably one of the most important meetings that we're going to hold. It's on regulatory thresholds. Where do we draw the bright line from a regulatory standpoint when a drug has produced resistance in animals that are now a public health threat to the public? And so we're going to have a public discussion on that. We expect that--we actually expanded that from two days to three days because we think we're going to need a lot of input from the public on that.

One of the areas--we've been dealing with this issue actually for about 25 years and it's a very--the reason that we probably have not made as much progress in that time as we would have liked to is because it's a very scientifically complex problem to try and regulate. It's a natural process that antibiotics do select for bacteria that are resistant to them.

There were actually three National Academy of Science studies that were conducted prior to 1996 in which the conclusion was, we don't know. We can't really determine what the public health impact of antimicrobial drugs are on the public health. We have concerns, but there simply is not the kind of data that are necessary to be able to concretely identify what the public health risk is. And they recommended that a lot more studies be conducted and that it would be a substantial cost to conducting those studies.

That's when we created a National Antimicrobial Resistance Monitoring System. It is an ongoing, day-to-day surveillance system to look at antimicrobial resistance as it comes from animals, food animals. We take samples at the slaughter facilities through the USDA's HACCP program. We send those to a central laboratory in Georgia, have those analyzed to determine whether or not they're resistant to 17 different classes of antimicrobials.

We also have the same system going on in the human side through the CDC FoodNet system, so that samples are coming in from the human population. We understand, we can identify what the resistance patterns are in humans, look at it in animals, try to make the determination whether or not there is a correlation between the use of the drug in animals and the resistance developing in people, and if we see that there is a problem, we can intervene early.

Some of the uses of the data from this system, which is absolutely critical--I would just say that it is absolutely critical to have this kind of surveillance system before you can have any kind of regulatory program because you have no idea if you take regulatory actions if they're actually having any benefit unless you have a system that gives you feedback.

But we use this data to initiate field investigations of outbreaks and there have been some outbreaks that would not have been identified quickly had it not been for this system. It provides background data for risk assessments, which we are relying more and more on to make sound regulatory systems. It has stimulated research, because as we find things, we ask more and more questions about how did we get to this point. It improves the knowledge of our risk factors. Once we identify the risks, then we can look and find out where along the chain the

greatest risk may have occurred. It triggers broader research in additional programs that I'll talk about, such as judicious use programs. And the program is expanding through the President's food safety initiative.

But the program is--the number one function of the program is to allow us to make good regulatory decisions, and based on this program and based on ours, we have proposed to withdraw one antimicrobial drug from use in animals at this time because we have evidence that resistance is occurring at levels that we consider to be unacceptable. And so in October, we did issue a notice that we intend to withdraw the approval, and that's it.

Judicious drug use--we're also cooperating with other organizations, such as the American Veterinary Medical Association, to educate and develop educational materials for veterinarians so that they maximize the therapeutic effect of antimicrobials when they're treating animals, but also minimize the development of resistance, and we are funding some of those educational programs and will probably do more of this in the future.

We're also looking at alternatives. Through the approval process, we're looking at alternatives to antimicrobial drugs and such products as competitive exclusion products. These are cultures of bacteria that are administered to animals that colonize the animals'

intestinal tract and compete with the bad germs, the salmonellas and the campylobacters and other pathogens such that animals, by the time they become food, should have fewer of these pathogens that might infect the public.

And this year in our appropriations bill, there was additional language inserted that said, give these kinds of products expedited review status because they are purely for public health purposes, and we intend to do that.

In addition to animal drugs, we also do something in food additives. We generally call those feed additives. We regulate all animal feeds, whether it's dog food, cat food, or feeds that are fed to chickens, pigs, horses, cattle, et cetera. CVM is in charge of the safety of all that food, and again, we are not only concerned about the safety to the animals themselves, although that is a primary concern. We are certainly interested in making sure that anything that goes into animal feeds will be safe to the consuming public.

BSE, "mad cow" disease, is one of the areas that we have dealt with. We've done this through regulations prohibiting certain animal proteins from being fed back to cattle in order to make sure that this disease does not occur in the United States.

We have other issues, such as dioxin and other substances that can potentially contaminate feed and present

a public health risk. This is a huge area. There's--when you think about how much animal feed there is produced in the United States compared to human food, it's staggering. Just the number of animals in the United States far surpasses the number of people in the United States. So it's a fairly broad responsibility.

So some of the challenges that we're going to be facing in the future, the whole issue of antimicrobial resistance will occupy our time for the foreseeable future. We hope to make a lot of progress this year. We certainly think that the meeting we'll have next month will give us a lot of guidance to what our next steps should be. In the meantime, we are not sitting on our hands and not taking action where we think that there are problems. Our goal is to protect the public health. We hope we can do this and still meet the needs of our animals who actually rely on us for making sure that they have the products that they need.

Finally, I'd just close by saying that the role of the consumer is to continue to participate. This is really important to FDA. This is not something that we just talk about. This is deeply ingrained in the culture of CVM and I think the rest of FDA, is that we want to make sure that we treat the public, all of our stakeholders or our clients or however you want to call it, that we don't favor one sector over another, that we are constantly in touch. When we

announce something, we want to make sure that it gets announced to everybody at the same time. We want participation. This is core culture in the organization. We want consumers to be better informed and better protected.

I think that I can close there with our following slide, basically repeating what I said. We do have a home page that talks about most of the things that I talked about today. We keep that updated and we encourage people to check in with the website frequently. Thank you.

MR. BARNETT: Thank you.

Dr. Wood?

DR. WOOD: Thank you for this opportunity to respond to Dr. Sundlof and the work of CVM. I also thank you for this meeting. Consumers, as we define ourselves, often participate in larger stakeholder meetings, as Dr. Sundlof expressed, and find ourselves very few in number in comparison to the other stakeholders in the room. Perhaps our voice is heard--I'm sure it is--but we often have the feeling of being overwhelmed and it's good to have this kind of singular and specific focus and opportunity for this kind of discussion.

FACT advocates for farm management systems that promote the safety of meat, milk, and eggs, organizations predicated on the assumption that healthy animals means

wholesome food for consumers. I'm delighted to see that CVM has adopted our mission statement for themselves.

We currently have about 30,000 individual supporters nationwide and we also sponsor a demonstration farming system on 12 farms in Pennsylvania with a salmonella enteritidis control program on these farms for layers, egg layers. We also now are working with hog farmers in the Midwest.

FACT has been involved and has responded to many of the CVM activities over the years and I'll comment on two areas at the center. It's work related to antibiotic resistance and to BSE.

MR. BARNETT: By the way, both of you said BSE, and there may be people who don't--you're talking now about what people commonly refer to as "mad cow" disease.

DR. WOOD: That's right.

MR. BARNETT: Okay, for those of you that are not veterinarians.

DR. WOOD: And I'm not a veterinarian, either.

We applaud the Center for Veterinary Medicine for making antimicrobial resistance a top priority. In our view, a benchmark for giving this concern greater priority for CVM came in a guidance document that really hasn't received much attention in and of itself, but it signaled a significant turning point in terms of CVM's relationship to

public health. It's Guidance Document 78, which was finalized, I believe, one year ago today, and it acknowledges that the use of microbial drugs in food animals selects for resistant bacteria that if transferred to humans can have an adverse effect on human health. The guidance document requires that applications for new antibiotics intended for food animals must now assess the potential human health impacts of the drugs, and that's new. This requirement, when implemented, in itself is a consumer protection act, as we see it.

The most recent and best example of CVM action on behalf of public health is illustrated in the proposal that Director Sundlof identified in the proposed ban on fluoroquinolones from use in poultry in light of recent sharp increases in resistance to fluoroquinolones in campylobacter bacteria. For those of you in the room who may not be familiar with this, campylobacter is the most common cause of gastrointestinal illness acquired through food in the United States.

Physicians have used fluoroquinolones as an essential treatment for foodborne disease since 1986, but fluoroquinolone resistance to bacteria were rare until after 1995, when FDA approved the use of these drugs in drinking water for poultry. I think you see the connection. By 1998, the CDC found that over 13 percent of the foodborne

campylobacter bacteria infecting people were resistant to fluoroquinolones, and last year, the resistance rose to nearly 18 percent, an increase linked to fluoroquinolone use in poultry and which is part of the basis of the new evidence that forms the basis for CVM's notice.

On behalf of a consortium of consumer and public health groups, I do thank Dr. Sundlof and the Center for Veterinary Medicine and the FDA for initiating this notice. We now call on the FDA for speedy action in implementing its ban, and the proof of this pudding lies in FDA's timely summary judgment on this question. As fellow consumer advocates, contact Commissioner Henney and ask for speedy movement on a ban.

Other CVM examples of implementing the Guidance Document 78 are more difficult for us to identify from a consumer and public health perspective. The framework document was introduced soon after the guidance document was drafted. The framework, if adopted by the agency, can be a useful tool for future approvals. It would provide the context around which consumers and other stakeholders could review and respond to FDA antimicrobial decisions using the same set of assumptions and criteria employed by the agency. Unfortunately, the framework is still not in place. Hopefully, the January meeting that Dr. Sundlof referred to on thresholds will bring us closer to its implementation in

some form.

Now moving to the other end of the spectrum, in our view, the most glaring failure of the Center for Veterinary Medicine to protect human health is in allowing the continued use of non-therapeutic antibiotics in food animals. We trust that the Virginia Miocene Risk Assessment that is now underway is a first step in addressing this issue, and yet we are still waiting for a response to a petition filed by consumer, public health, and leading physicians on March 3, 1999, requesting that the Commissioner rescind approvals for sub-therapeutic antibiotic uses in livestock that impact human health therapies. The sponsors on that petition were consumer groups that included the Center for Science and the Public Interest, Environmental Defense, Public Citizens Health Research Group, Union of Concerned Scientists, and FACT.

Many of these same groups, among others, supported the $3 million appropriated to CVM for its fiscal year 2001 antibiotic resistance work, and FACT was pleased to learn that the center apparently intends to use these funds to target several approved animal drugs for safety review, followed perhaps by possible withdrawal from the market.

There is no question about FDA's authority to withdraw a drug from the market, but if CVM needs a framework for action on its prior approvals of non-

therapeutic antibiotics, we encourage FDA's support of legislation similar to that introduced in the last session of Congress by Sherrod Brown. This legislation directs that essential antibiotic drugs are not to be used in livestock unless there is a reasonable certainty of no harm to human health, Guidance Document 78. The legislation clearly provides FDA with the statutory authority to act and gives both FDA and the industry a time line for such a review.

Finally, we call for the public disclosure of antibiotic sales information. Health officials have indicated that a major obstacle in assessing the link between animal drug use and rising resistance is the lack of data on how extensively antibiotics are used in food production. One only has to look at the debate that's going on right now around fluoroquinolones in poultry, where on the one hand, health officials are finding resistant campylobacter in broilers at the supermarkets, and yet the poultry industry is saying that they aren't using the drug all that much. How much is Baytril being used on poultry farms? What is the volume of doses used per hen? Regarding sub-therapeutic drugs, licensed feed mills report the pounds of feed sold, but how much active ingredient is in the feed?

It is time for the industry to stop playing shell games when it comes to their food animal use of antibiotics impacting human health. CVM must require the reporting of

specific sales data that could also be available to the health community and to the public.

The public has at least two important functions when it comes to defining how antibiotics are to be used with animals. First, consumer representatives should be at the table along with scientists and other stakeholders to define the criteria by which an antibiotic for food animals is approved. For example, should resistance testing be a part of the approval process? What kind of provisions are in place if resistance were to occur?

Second, consumer representatives should be at the table to help identify the threshold for antibiotic resistance. At what point of resistance is an antibiotic to be considered a threat to public health? These and other roles are critical for consumer involvement.

FACT is also concerned about any steps taken to expedite the animal drug approval process. Once a drug is approved, it is rarely removed from the marketplace and the process of removing that drug can often take years. The approval process must not be truncated for expediency's sake. Both the public and animal health may suffer in the long run and may ultimately lead to unhealthy animals producing unwholesome food.

I've been at FACT since 1995 and in these few years, I've heard CVM officials on two occasions lift up a

concern of great importance to consumers as CVM's top priority. Today, we heard that antibiotic resistance is CVM's top priority, and as I've stated, FACT welcomes that priority and that emphasis.

The other recent occasion for CVM setting up a top priority recently followed the adoption of the rule to prevent the occurrence of BSE, which is bovine spongiform encephalopathy, or "mad cow" disease, in U.S. cattle. At that time, the center vowed to implement an intensive inspection process of feed mills and rendering plants and many steps have been taken by CVM in that regard. Most notably, I understand that 9,000 inspections of feed mills, cattle producers, and renderers have been completed over the last couple of years.

I remember taking part in a teleconference designed to train feed mill operators in this regulation. But a recent GAO study found that more needs to be done. The GAO reported that in these inspections, the FDA found over 18 percent of the firms surveyed were not aware of the regulation that was adopted in 1997, including 11 percent of the renderers. So much for the teleconference. Twenty-eight percent of all those surveyed did not label their products with the required cautionary statements that the feed should be not fed to ruminants. Twenty percent of the firms did not have a system in place to prevent commingling

of ruminant feed materials with non-ruminant feed materials.

Further enforcement steps must be taken by CVM as soon as possible. It is time to move beyond education and warning labels to enforcement and to the penalty stage. I understand that a rule addressing animal feed is being drafted, but there's no time line for it being published or even discussions with stakeholders, as far as I know.

At the same time, the science around the "mad cow" disease, BSE, continues to emerge. Careful attention needs to be paid to the eight new BSE cases in Britain or the spread of the disease may possibly be linked to cow blood in cattle feed, a protein source that is allowed in feed for U.S. ruminants.

In conclusion, we will soon see a change in the administration, I think. Some significant building blocks--significant building blocks--to protect public health have been put into place over the last few years by CVM. The next administration must cement those blocks together so that CVM can fully respond to both animal and human health. As these steps take place, it is our hope that consumers are involved in the building process all along the way. In our view, the greater the involvement, the better the final structure. Thank you.

MR. BARNETT: Thank you, Dr. Wood.

Before we go to lunch, I want to open the floor to

questions and comments again. Do we see a hand? Yes, sir, right up on the aisle. Identify yourself, please.

DISCUSSION

MR. GOLDBERG: Adam Goldberg, Consumers Union. We do believe that FDA should act to phase out medically important antibiotics that are used in animal agriculture to promote growth and compensate for unsanitary growing conditions. To that end, the fluoroquinolones. We do think that FDA should act promptly to finalize its proposed ban and I was just wondering what the time line looks like.

DR. SUNDLOF: Well, the next time line is January 2, and that's when the one company that has the approval has to provide us with the basis for their position that the drug is safe. At that time, we review the information that they provide us and that time frame will largely depend on how much information they provide, but we will be reviewing that as quickly as possible.

Then following that, we will publish a notice of hearing and that notice of hearing will state the time and the place and the date of the hearing, at which time there will be a hearing before an administrative judge and that process--how fast that process occurs is largely a matter of the courts at that point, so that I don't have much control over the legal process at that point. But it is our intention to move as quickly as possible.

MR. BARNETT: Another one? We have no takers? If that's the case--oh, we do have one more. Okay.

MR. KAY: My name is Brett Kay. I'm with the National Consumers League, and the question I had, Dr. Wood, you had mentioned that a large portion of renderers and others in the animal feed business had not been aware of a lot of the regulations concerning ruminant feed and other issues related to BSE and I just wanted to ask Dr. Sundlof what the FDA is doing to follow up to ensure that all of the animal feed manufacturers, particularly those renderers, are aware of the regulations, particularly ruminant-to-ruminant feed and other issues that might affect BSE.

DR. SUNDLOF: The idea is to--let me just tell you what the whole plan is. The whole plan is to inspect 100 percent of all firms that handle these prohibited materials except at the farm level, where there will be just too many farmers mixing feeds. But we do a lot of spot checking on those. But everybody that's a renderer has been inspected, is my understanding. Those that were found not to be in compliance are being reinspected to make sure that this time they are in compliance.

It's most important for the renderers to be in compliance, because if they don't label their product, everything downstream from there, people can't comply with the rules. So we take this issue fairly seriously, and

having 100 percent inspection is pretty unusual for FDA, but you only have to look to Europe to see what kinds of problems it can get into.

And the issue in Europe is it wasn't that they didn't have strict laws. The problem seemed to be--the reason that we're still continuing to see the disease appear in Europe is because they didn't have good enforcement. So it was an enforcement issue. At least, that seems to be the thinking. I think we've learned a lesson from that and we intend to make sure that that same problem doesn't occur here in the U.S.

MR. BARNETT: Did I see another hand up here? If not, let's go to lunch and let's be back and begin again at 1:30.

[Luncheon recess.]

AFTERNOON SESSION

MR. BARNETT: If you'll find your seats, we'll get started again.

Our next center in the FDA is the Center for Drug Evaluation and Research and its Director, Dr. Janet Woodcock. Our lead respondent will be Cynthia Pearson of the National Women's Health Network. Dr. Woodcock, I'll leave it to you to start and we have a 15-minute guideline for time.

CENTER FOR DRUG EVALUATION AND RESEARCH

DR. WOODCOCK: Thank you. Good afternoon, everyone. It's a pleasure to be here. I was asked to speak, as were the other speakers, about FDA's priority, and for me it's in the area of drugs.

What I want to say to you is the following. We think our priorities are the public priorities, or we try to make our priorities the public's priorities. We feel that's what we're here for, is to serve people who take medicines and what their priorities are. And what they tell us, what they have told us, because we have tried to listen very carefully, people want safe, effective, cheap, fast, and available drugs, and they want them to be accompanied by extremely clear and unbiased information about the drugs.

The public definitely wants safe drugs, and the emphasis that people put on the safety of drugs really

relates to how urgently they feel they need the medicines. People who have severe illnesses or feel seriously compromised by their illness tell us, in general, that they are willing to assume greater risks than people who are going to take a medicine for a headache or for a toothache or something, and that balance is something that's very difficult for us to manage because people want the risk of medicines to be managed.

That's really the definition of safety, that adequately safe drugs are put on the market, and for those drugs that are on the market, all of which have risks, that those risks be managed. In other words, people are informed of the risks, they understand what measures can be taken to avoid the risks, they feel their doctors are fully informed about the risks, and so there is a complete understanding of what risks are taken in order to get the benefit.

Another thing the public wants, another part of safety is that the quality of medicines be assured, and the issues around quality most recently have arisen with regard to imported drugs. There is a concern of counterfeiting drugs and those counterfeit drugs being imported from outside the country. There is concern about the quality of drugs that are perhaps manufactured around the world and imported into this country, and FDA and the Center for Drugs and the field organization are in charge of making sure that

that quality is assured. That's definitely a big part of safety of medicines.

Another part of safety is that people are safe because health fraud is being pursued. Over the recent years, FDA's ability to deal with health fraud has lessened because of our resource constraints. We've also shifted a lot in the drugs area of our health fraud resources into pursuing drug sales on the Internet, which was identified as an emerging threat to people's safety, particularly the sale of prescription drugs directly to consumers over the Internet. And so while one part of safety is the issue of dealing with health fraud, I think that's something we haven't been able to address as stringently as we would like in the recent years.

And also, appropriate advertising. Part of safety is that people are not misled through advertising about the benefits or the safety of the drugs that they use, and, therefore, a regulation of advertising to ensure that it's appropriate, truthful, and balanced is an important part of safety.

Now, there's been some concerns about one aspect of safety which relates to newly-approved drugs and consumers have raised this point repeatedly, that they're concerned that the increased speed of review of new drugs is leading to increased drug withdrawal rate. And we've

published this information before, but I thought I'd put it up here.

You can see on the far right-hand column, there is a percent of drugs that have been withdrawn from the market based on the year they were approved in five-year brackets, and you can see that the rate of drug withdrawals has not increased over the years. Nevertheless, the number of drugs that have been approved has increased, and, therefore, the absolute number of drugs withdrawn is going up.

In addition, FDA and the Center for Drugs, I think, is taking a more aggressive attitude toward drug safety over the last four or five years. This has resulted in older drugs being withdrawn from the market as well as newly-approved drugs being withdrawn from the market, and partly ironically, I think, this increased posture toward drug safety has led to increased concern, because more drugs actually have been withdrawn overall. But these drugs have not been weighted toward recently-approved drugs.

Now, lately, over the past few years in the context still of safety, the FDA has been talking about risk management, and we mean a number of things by risk management. We think it's no longer acceptable for anyone to just say that drugs are safe and effective because that is misleading. It's not possible for any drug to be 100 percent safe.

We have been aiming toward a broader recognition throughout people who take medicine and the treating community, the clinical community, of the risks of drugs that are out there. These risks are detailed in long lists within the package insert, which many of you may have seen if you look in the PDR, but we don't feel that the recognition of these risks has really penetrated into people's consciousness the way it needs to be to be dealt with.

Another aspect of overall risk management of drugs is the fact that for many drug classes and for patients with many different diseases, there are a lot of alternatives available. And once that happens, once there are many alternatives available for a given condition, you start thinking more about looking for the most safe alternatives, the best alternatives, rather than concentrating on getting some drugs out there to treat the condition. And this is somewhat of a different ballgame than just looking at overall effectiveness and safety. This is looking at which drugs stand out as far as having an inferior risk profile, and what should be done about that.

And the consequence of that, and that's my third bullet, is that what you're going to begin to see is that some older drugs will become obsolete as safer drugs are approved and appear on the horizon, and our attitude in risk

management is that we can't just sit by and hope that the clinical community won't use these drugs. We need to move aggressively and perhaps get these drugs off the market.

If I can go over just a couple, Mark, if I'm keeping in my time here--

MR. BARNETT: No, we're okay. I'm watching.

DR. WOODCOCK: He's looking at his watch already--at recent safety-related actions that we've taken with respect to drugs, the drug Rezulin was removed from the market. It had been the first in its class of a novel class of anti-diabetic drugs, but it came with a cost, a price of a rare but often fatal liver toxicity and that drug was removed from the market when safer drugs in the class became available that offered the same benefit but did not carry that risk.

Phenylpropanolamine, or PPA, you all may have read about. That was an over-the-counter ingredient. It was in--many of you have taken it. It was in many, many cough and cold type of remedies and some weight loss, over-the-counter weight loss drugs. It had long been under a cloud, though, because of possible association with a risk of hemorrhagic stroke, and when additional epidemiologic data became available that strengthened that connection, we put out a public health announcement urging people not to take this medicine and many firms have withdrawn it from the market.

We will have to go to rulemaking to actually remove it from the market and we intend to do that.

The drug Accutane, again, another safety-related issue. The drug Accutane has been on the market for several decades. Accutane is a major human teratogen, which means it reliably causes birth defects, serious birth defects when taken in a certain stage of pregnancy, specifically in early pregnancy. The FDA over all this time, despite fairly significant efforts, was still getting reports of babies being born with birth defects as a result of Accutane, an event that is entirely preventable. In addition, the drug has recently, over the past six or seven years, felt to be associated with some severe psychiatric side effects.

As a result of all this, we had an advisory committee this summer and we're implementing with the company a really unprecedented series of restrictions on Accutane distribution that will be designed to try and overtly prevent birth defects from happening at all, and also will make sure that anyone who takes Accutane is completely aware of the risk of the psychiatric effects as well as other major side effects that Accutane may carry.

Finally, the drug Lotronex was recently withdrawn from the market. That was not our preferred option with Lotronex but it had developed some serious side effects that were found to be more serious after the drug was marketed

and we could not agree with the firm on an adequate risk management program for this drug. But again, as an example, we rapidly responded when safety information became available.

I could go on and on about drug safety. There are so many facets to drug safety. Another aspect that we're working on in drug safety and many other people are is the whole issue of medical errors. This was highlighted by the Institute of Medicine report that came out a year ago. The AARP just put out a booklet on this where they said that about 50 percent of the adverse events in hospitalized patients that were preventable in the elderly were due to adverse drug effects. That's 50 percent of the bad errors that occurred to elderly in the hospital.

And most of them were not what you read about, where the pharmacist gives the wrong dose to the patient. These were errors where the elderly were given inappropriate drugs, drugs that are known to have a bad effect in the elderly, or where the elderly were not monitored appropriately to make sure that bad side effects did not develop in them.

So one of the problems FDA's facing in wrestling with in the area of medication safety is how medicines are actually used out there. How are they used? How can they be used safely? This is, as the Institute of Medicine has

identified, this is a very serious problem for a health care system.

Now, we all agree that this problem is not going to be amenable to blaming different people--blaming doctors, blaming health care systems, blaming the FDA for the way medicines are used. There is a consensus, I think, of people who are working on this that we have to get beyond blame and go ahead and try to make serious modifications in the way health care is delivered that focus on safety, and that would help us tremendously at the FDA in medication safety, if this can occur.

Unfortunately, one of the things that probably for medicines, greater safety of medicines, is going to partly be coupled with decreased prescribing autonomy for the clinical community, and this is a very difficult subject that we are trying to deal with and we expect that--we already have gotten a great deal of push-back on this issue where we're trying to do restricted distribution for certain drugs.

Now, the public doesn't just want safe drugs, and I hope I've given you some understanding of the different fronts that we have to labor on to make sure that drugs are safe. They want effective drugs, drugs that work, and that is a long fight that we've been engaged in for 40 years, ever since the drug amendments were put into effect

requiring that drugs be studied to see if they work. We still are working to make sure that drugs get studied adequately and they have proper end points and standards when they're approved to make sure that drugs are effective and we know enough about their effect.

Right now, I think the clinical pharmacologists tell us they don't believe the Center for Drugs approves drugs that aren't effective. So in some ways, that battle has been won, but there are new battles. Effective for who? We know when we approve a drug, it's studying a population. It's not going to work for everybody, and there might be ways to identify who that drug will work in and that's probably one of the next frontiers in effectiveness.

The next bullet we have, the similar issues as we do for safety and effectiveness in that some drugs are becoming obsolete in their effectiveness. The public definitely wants the drugs of today. They don't want 100-year-old drugs unless they're still really good, like maybe aspirin.

Quality that I talked about earlier is also important for maintaining effectiveness of drugs, and we still have problems, different quality problems, and the FDA labors to oversure [sic] the manufacturing of drugs, proper manufacturing, and make sure that quality is maintained and that effectiveness is maintained for people.

But overall for the public that takes medicines, it's most important that we focus on improving the armamentarium, in other words, improving the quality, the effectiveness, safety, quality of drugs that are available to the public.

MR. BARNETT: We're getting close.

DR. WOODCOCK: Close? Okay. I'll go really fast on the next few slides.

The public also has told us they want drugs to be available to them and accessible, and I know some of the consumer groups in this room may have different opinions on this and I'll be very interested to have a discussion about this. Everybody agrees in general that generic drugs, if they're adequately equal and switchable to the innovator versions, provide economic access and lower the overall costs. That's been proven of drugs. And so our generic drug program is very important to us in lowering the cost of drugs and providing access to drugs.

OTC drugs, for a large segment of the public, including me sometimes when I want some drug, it's very nice and convenient to be able to get that drug over the counter and not have that huge barrier to some people to having to get it through the health care system. If self-care can be delivered by the person to keep that drug safe and effective, that is very important to access.

Many people feel that availability of drugs shouldn't be impeded by delays in the review process, and that's the other side of reviewing drugs "too fast," is that prolonged delays in the review process that occurred in the past delay the availability of drugs to people in the United States.

And finally, a lot of people want investigational drug access. That's what the public tells us, people who are sick and don't have alternatives. We are continuing to work on this to make this work safely for people but also to give them access to investigational drugs.

As far as low-cost drugs, we struggle in our program because we have ongoing efforts by the innovator companies to thwart generic competition and we are spending a tremendous amount of effort that we didn't have to spend in the past, the legal effort and our staff's scientific effort, in order to deal with these disputes. It takes a tremendous amount of time. We are under pressure from the pharmaceutical industry because they actually have a need to decrease their research and development costs because they are under price and cost pressure.

And finally, there are many people who believe that direct consumer advertising is driving up costs, and I want to talk a little bit in the next slide about direct consumer advertising. I want to point out, because people

may not realize this, it's always been legally permissible in the United States to do direct consumer advertising. This isn't new, it's just the volume of it that is new and it's in your face now--I saw some on the Metro when I was riding down here--and people are disturbed about this.

We are trying to study the effects of this increased direct-to-consumer advertising. We find that it's a double-edged sword. We find that untreated populations, of which there are many in the United States--probably half the people in this country have cardiovascular disease are inadequately treated, and we're talking about life-saving therapies that aren't reaching them. On the other hand, there's a concern that direct-to-consumer advertising will lead to inappropriate prescribing of drugs and, thus, increased side effects and so forth.

Unfortunately, CDER doesn't have the resources to do the scientific evaluation of the impact of direct-to-consumer advertising that we would like to do, and so much of the debate on this is left at just debate and different people's opinions and we don't have a lot of data on the scientific impact. We have data on the cost impact, but that's only part of the equation.

I'm almost done, Mark.

We also have heard the public wants good drug information and they would like to hear from FDA about

medicines because we are an unbiased source, at least presumably unbiased source, of information about medicines. We have been trying more in the recent years, in the recent six years, sa, to provide more information, but we aren't doing anywhere near what we would like to do.

We had a public meeting, I think three years ago in this very room where a representative of the pharmaceutical industry stood up and said CDER has no business informing consumers about drugs. So there are different groups who have different opinions about what we should be doing, but what we've heard from the public is that they would like to hear our assessment of medicines. And, of course, we do much of that assessment with the taxpayers' money.

This just goes through--we're really trying in many ways. The over-the-counter label is being implemented on over-the-counter products now. It's going to look like the food label. It'll really give that information on over-the-counter products in a way that people can understand.

We hope to propose very soon a revision to the drug package insert, the part that you read in the PDR or is stuffed in the box of your drug, the long, skinny thing, that would make it readable. I see some smiles in the audience. It isn't readable now, we agree, we understand, but we hope to propose that. We have to do that under

rulemaking.

The med guides, which we finalized the rule last year, which allows us for a handful of drugs every year to mandate consumer information that has to be given out to the patient by the pharmacy, we think that's a good start, and we're going to try to strategically use different regulations and guidances to figure out ways to get more information out. We understand there's a great hunger there for balanced, credible information on drugs.

The last one. Finally, I'm supposed to talk about our goals and priorities for 2001. I'm not going to bore you with our very specific initiatives, but internally, we need to support our people and we're working on that as part of the Commissioner's science-based initiative. We are improving our processes. In particular, we're doing more things electronically, many more things, including our processing of all the 250,000 reports of adverse events from drugs that we get every year. You can see that you definitely need a computer system to process and manage all those. And we're doing investments in our future as an organization.

But externally, I have told the center that one of my highest priorities this year is to have better outreach and build those external ties, really listen to all our different constituencies, medical community, nursing,

pharmacy, consumers, patient groups, and so on, build those ties so that we really are making sure that our priorities are your priorities. Thank you.

MR. BARNETT: Thank you.

Ms. Pearson?

MS. PEARSON: I'm not using any audiovisual aids, so if you want to bring the lights back up, it might help people stay awake after lunch. Thanks.

I'm Cindy Pearson. I'm the Executive Director of the National Women's Health Network. Many people in the room know the Network, but for those who don't, we are a national organization advocating for policies that protect and promote the health of all women and which also provides evidence-based independent information to empower women to make fully informed health decisions. We're supported by a membership of nearly 10,000 people nationwide and we accept no money from companies that sell pharmaceuticals, medical devices, dietary supplements, health insurance, alcohol, or tobacco.

I'm very pleased to be able to lead off the consumer response. I appreciate also very much having a chance to see Dr. Woodcock's planned remarks in advance, which I know everyone did. They're up on the website. I appreciate that. We're trying in these remarks to sort of span a response to the issues you've brought up and bring up

some other issues that are of concern to us specifically, also other consumer groups that we network with, many of whom are here in the audience, and I hope we'll get a chance to have a dialogue going after our opening response.

Since the Network was founded in 1975, and there are people who were involved in that era right here in the audience, we've closely monitored CDER. At times, we've been among the sharper critics, but we also feel that we are strong advocates for making expanded resources available to the center to pursue a goal that we believe we share with the FDA of ensuring that the drugs that are available to U.S. consumers are safe and effective. And so the comments I'm giving today reflect that tension, that at times we are critical, but we also believe that CDER is underfunded and they're not able to do the job that it wants to do.

So to lead off with drug safety, Dr. Woodcock has already mentioned and already put some data up about consumers' expression to the FDA that some consumers believe drugs have become less safe under the current era of pressure to approve them quickly, and we can read statistics. We acknowledge what your statistics show us. But I think we need you to hear also that we believe we see other ways in which the safety process has been overridden, at least at times.

We believe we can see examples and can discuss at

length examples in which drugs have been approved, even after FDA review staff have recommended against approval. Drugs have been approved when FDA staff was not given sufficient time for approval due to foot dragging in submitting data on behalf of the sponsor. And drugs have been approved after being recommended for approval by the advisory committee, but the advisory committee was not given access to all the important information that the agency and the sponsor had.

And so even, I think, underneath the summary statistics, consumers who watch the FDA can believe, as we do, that there are some problems that are still there that could potentially be changed and not be there.

We would also like, in terms of drug safety, for the center to work more closely with consumers and consumer advocates during the approval process. We believe that the consumer representatives that are currently on the drug advisory committee should have a vote. We believe that there should be more open public forums for discussions of drug approvals. We have a perception, at least, and this may be in the area of women's health, that the percent of open public meetings to the percent of approved drugs has dropped recently.

And we'd also like, in this age of the Internet and instant and easy availability, we would like for

consumers to begin to have more timely access to information that's provided to the advisory committee for their approval. It's not all proprietary. Some of it's going to be discussed in public and there's no real scientific reason why it needs to only be revealed to the consumers and the world at large on the day of the meeting.

And with respect to risk management, we agree. We know there was no golden era of all safe drugs. Every drug that's ever been approved, no matter how slowly, brings some risk with it. But we believe that with respect to risk management, it's very important to expand and make it appear to the consumer that risk management efforts are being applied consistently.

We have a recent example of mifepristone, which was recently approved for use as an early abortive agent. That's a very high profile example of a risk management strategy applied right up front at the time of approval, and the National Women's Health Network supports several methods that you used in that risk management strategy, such as the written patient agreement, the med guide requirement.

However, it's unfortunate that it came at a time when there had been little widespread experience with that high profile kind of risk management strategy because it makes it appear that mifepristone has been singled out, either because it's such a political hot potato or, and I

hope this isn't true, because the FDA believes that women seeking abortions and clinicians providing abortions require closer supervision than consumers and other sorts of health care providers do in general.

So just the message there is we like this. We'd like to see more of it. We'd like to see it more consistently throughout drugs, and if I can just take advantage of sitting here, saying also in devices and the other areas where the consumer is involved in making the decision.

On drug efficacy, I think historically we've had fewer quarrels with the agency, consumers in general. But I will say now, as the United States pharmaceutical industry sees the demographic bulge of this country move into middle age and has an interest in providing drugs for prevention in addition to providing drugs for treatment and cure, consumer advocates are beginning to raise concerns about what is the definition of efficacy and how often should we take our interest and the pharmaceutical companies' interest in getting drugs out quickly, which means that the definition of efficacy is an intermediate endpoint. It's cholesterol lowering or mammographic density or bone density, but how often should we push and say, we want to see that the condition is affected. If we are going to begin taking this drug as healthy and it has risks, because every drug does,

shouldn't we have a proven benefit of an actual health condition, since that's what affects our life as a healthy consumer.

And I want to comment in here some of the tension about being supportive and agreeing you need more resources and agreeing with your mission and then the tension of same sometimes. We just have to disagree. That cute slogan of consumers want drugs of today, not of a century ago, we do want drugs that work and there are conditions for which drugs don't work, so we would love some new drugs there. But we don't want new drugs just because they're new.

And the fact that that idea is getting out there is, in our opinion, and we get the freedom to say this, just a drug company marketing tactic. It benefits the pharmaceutical industry hugely to be able to come out with new drugs because that's the era when they have patent protection, when they can advertise heavily, make very large sales, and make quite a huge profit.

On the other hand, consumers, as long as there are some drugs available for the condition, benefit from using older drugs. They're better known. We know what the adverse reactions are. We know who shouldn't be using them.

So you're right. We are all for your consumer surveys that have given you information that leads you to say consumers want the drugs of today. You're right that we

want innovation with new products that offer a genuine improvement. But we don't agree with the claim that new is always better.

We also want to give some feedback here on encouraging development of products for the public health, and this is something that doesn't bubble up as a priority in your very overstretched center because there's not much push for it. There's certainly public health products that could be developed that would do enormous good for the world, like a microbicide, for example, that women and men could use to protect against HIV infection when condoms aren't an option. Some of those products are perceived to be not having a large market or a large affluent market and we believe that those of us in the public health arena that have to do our advocacy work to push for this kind of product development could benefit if the FDA would proactively release approval guidelines.

Obviously, you're not developing the drugs. You can't make it happen all on your own. But if you put out there a clear statement of what kind of trials would be required, what kind of steps need to be taken, and we have had some successes working with the center on some issues.

On the issue of low-cost drugs, how can we disagree? Everyone would rather their drugs were cheaper and we love those drugs that we can get cheaply, but we

believe it is not appropriate for the FDA to posture itself in a way that implies that it is responsible for the high cost of pharmaceutical products. The FDA can take action to lower costs by approving--they're whispering, but they do. They do. They keep saying we are. Well, you can approve more generics and we very much thank you for devoting full-time legal staff to fighting off the attempts to thwart you from approving generics.

But we do not believe that the FDA should consider compromising its standards for approval and balancing that against cost. It's critical for consumers that the FDA maintain the high standard that it has for demonstrating safety and efficacy, and industry complaints that the cost of doing research necessary to obtain this approval drives prices up are a little bit specious in light of the fact that this industry has higher profits than any other sector of American industry. Those profits are also calculated after research and development costs are taken into account. So we could say, perhaps, prohibiting direct-to-consumer advertising could lower costs, since companies would no longer have the billion-dollar-plus expense of running those ad campaigns, but we understand that might be somewhat controversial, too.

On direct-to-consumer advertising, the National Women's Health Network shares concerns with other consumer

groups that are here in the audience about direct-to-consumer advertising. You talk about it as a double-edged sword. We're seeing mostly the other side of that sword. We're seeing mostly inappropriate ads that overclaim benefits, that minimize risk, that misrepresent the intended audience or indication, and we understand that you have requirements for accuracy and balance and those requirements are necessary, but they're not sufficient. They're not doing the job. Advertising is designed to sell products. It's not designed to meet that other side of the sword of giving all comprehensive information.

In 1999, industry spent $1.8 billion in direct-to-consumer ads. It's on track to spend $2.5 billion this year. There's no kind of public health education campaign that can balance that out, that kind of sophisticated, effective advertising at that level.

You mentioned that CDER doesn't have sufficient resources to conduct the scientific evaluation of the impact of this. We're concerned--we think the resource problem is even more serious, that you don't have the resources back here to monitor the ads that are out there or to enforce those standards that you do have. Once a bad ad has aired, the genie is out of the bottle. That image that's been so cleverly crafted by brilliant advertisers is in people's brains and there's no way to ensure that any after-the-fact

action by the agency will correct the misleading or incomplete information that's already been received.

Under this current scenario, companies have little incentive to produce advertisements that are fully accurate, and we recommend that CDER improve enforcement of existing standards and institute a requirement for preapproval. That's controversial. You may feel you don't even have the authority, but we want to put it out there that we think that this would be an improvement and would protect consumers.

You can also consider a policy that I know other consumer groups would like to speak to in the question section of three strikes, you're out, you know, for the companies that keep making mistakes--mistakes, keep giving mistaken information out. Just cut them off.

We recognize that what we're asking for requires more--she's just laughing. We're in the consumer world. You're asking us what would help protect us. We're going to tell you what we think and get it into the discussion.

And we're also going to say something that's painful to say, because we want CDER to keep doing everything it is already doing on drug safety and effectiveness, but we think this issue of resources for direct-to-consumer ads is you may have to rob Peter to pay Paul and you may have to move existing resources around in

the agency while we go out and fight to get you more resources.

And the last specific issue I wanted to address is the drug information and the things that you were talking about at the end. We're really delighted that the OTC label is coming. The United States public is used to seeing the food label now and will be delighted to see something like that on over-the-counter drugs.

We've been advocating for med guides along with some of our colleagues in the audience for decades. We're happy to see you trying to get a rule through on those again. We're happy to see that you're starting to implement a handful a year. We'd love more. We believe that patients and healthy consumers can be important influential partners with their clinicians in managing risk if they get information in a usable format. So good luck moving that forward. We're with you all the way.

Just to summarize, I mentioned five goals that I think consumers have for CDER in 2001, five areas: Increased consumer input into the drug approval process; development of guidelines for approval requirements for classes of drugs that industry is not breaking down your door to look at but would have an important public health benefit; post-approval risk management of drugs, strengthening that, continuing your work on that;

prohibition of direct-to-consumer advertising or improved enforcement of direct-to-consumer advertising standards; and faster progress towards implementing the planned requirements for better consumer information. You should be able to do that, right?

DR. WOODCOCK: No problem.

MS. PEARSON: So, I didn't get yelled at for going overtime.

MR. BARNETT: No, you did really well. You weren't overtime. Thank you very much, Ms. Pearson.

Now, let's open it up for questions. Wow, okay. We're not going to be able to take them all. Let's start on this side--

MS. PEARSON: Do your best.

MR. BARNETT: Well, it's somebody who hasn't asked a question before. Okay, right there.

DISCUSSION

MS. ZUCKERMAN: I'm Diana Zuckerman from the National Center for Policy Research for Women and Families. In addition to agreeing with everything that Cindy Pearson has said, I wanted to focus a little bit more on direct-to-consumer advertising and the information available to consumers, and this is an issue for drugs as well as devices, but I didn't have a chance to say anything this morning.

I agree with Cindy that the ads that are being promoted for consumers are not providing information. They're the best persuasion that money can buy. That's what they're for. Let's not kid ourselves. And if you have a print ad in, for example, a women's magazine telling you how great a particular product is in the most persuasive way and then you turn it over and in microscopic writing you have a whole lot of words that you can--I speak for my aging self here--can barely read, but that even 20-year-olds can't necessarily read, either because it's too technical or they're too smooshed together and there's so much of it and they're so small and it's clearly not intended to be read and understood.

So somehow, these ads have to be done in a way that actually provides warning information for consumers, and I believe that one model we should use are the boxes that have warnings for cigarettes, where you have a clear warning of something important on the front page and then you might still have a back page, but it wouldn't be so crowded and the writing wouldn't be so small.

And also that the FDA really needs to do more in terms of its providing information directly to consumers. I think the RU-486 example is an excellent one. As far as I know, the LASIK surgery also look very good to me. I don't know nearly as much about that issue, but it seems really

clearly written, something that consumers could understand and give them a good sense of what's good about this product and what isn't so good.

And so we need more of that clear language, perhaps coming from the FDA, clearly stating what the risks are of a product as well--and let the advertisers talk about the benefits--and reaching out to consumers in a variety of ways, and not just the Internet, although that's an excellent way, I think, but reaching out to the press and to others that you don't necessarily reach out to. I'll give one quick example.

I was asked to be a luncheon speaker at a press luncheon for women's magazine health editors a few months ago on breast implants and I suggested that the people putting this together also invite someone from the FDA, a scientist who had just published new research showing a very high rupture rate of breast implants, and that scientist was invited and the official word was that she could not present at this luncheon because it was not a scientific forum.

Well, okay, but let's face it, if you want to reach out to consumers, you have to reach them where they are and a lot of women read women's magazines and these magazines promote many drugs and breast implants and some other devices very, very heavily. They advertise them and they write about them and they're getting a lot of hyped

information and they aren't necessarily hearing the other side. So here was a perfect opportunity for someone from the FDA to be there and talk about her new peer-reviewed research and it didn't happen.

Just as a footnote, a writer from Glamour magazine was at that luncheon, asked me who she should speak to at FDA, ended up interviewing Dr. Feigal, hence he was in Glamour magazine, but wouldn't it have been better to have her hear directly from the scientist who had done the research and get clear examples of what was going on?

So I ask you to reach out to the women's magazines and other magazines and other reporters that you wouldn't normally reach out to. Thank you.

MR. BARNETT: Thank you. Okay, another one, someone who hasn't participated before. Back there.

MS. CLANCY: Thank you. I would like to speak on behalf of those who are not represented and that being the general public. I worked in community health for 25 years and--

MS. PEARSON: Could you introduce yourself, please?

MS. CLANCY: I'm sorry. I'm Joan Clancy. I was a former representative on a consumer committee. I worked for 25 years in community health and 40 years in nursing, and I think one of the biggest open wide links is the fact that we

cannot get the message across to people. To the mothers in maternity patients, we would sit there and talk to them about the most basic things of how to take simply vitamins, prenatal vitamins, how to take birth control pills, and they just don't get it.

There is a plane there that we have not gotten on effectively, and you can talk about magazines, but there's a big portion of the population who will not buy a magazine, cannot buy a magazine, does not read the newspaper. Maybe television is their really only communication. It at least gives them some possible information.

Now, I'm not saying that all drug companies present in the very most uncovert way, but it still brings a presentation to probably most of our people now and I think that if we can heighten that to where they can bring information on an easily understood level--I mean, I think we all know the frustration just with AIDS, of how difficult it is to get to that. How difficult has it been for us to immunize our children? When you talk about adverse side effects, it's the same thing. We just aren't educating in that level enough.

We can sit here in meetings like this because we all come from somewhat of an equal background. But when you're in a general population, you don't have that, and we need to somehow be able to infiltrate and get into that

area. I don't know whether you have to start with children or where, but that's an area that we definitely need to invade.

MR. BARNETT: Thank you. Someone else who hasn't participated before? This gentleman back here, maybe?

MR. CLEMENTE: Hi. Frank Clemente at Public Citizen. On direct-to-consumer advertising, my understanding is that the FDA has had in process some regulations guiding what industry can say to the public. The guidelines that you have now, my understanding is those simply apply to what the industry can say to medical professionals, and I believe that's inadequate for the public at large.

My second question has to do with FDA, I think it was from 1982 to 1991, you used to keep track of new drug approvals and record whether a new drug had an important therapeutic gain or a modest therapeutic gain or no gain at all, and what you found back then was that 50-plus percent of the drugs were "me too" drugs. They had virtually no therapeutic gain. And as you know, in this world, with increased drug advertising and the changes in the drug industry and the marketplace, they want to produce a lot more blockbuster "me too" drugs. They're cheaper to produce. They don't have to do as much research, but they can make a lot more money off of it.

And so what I'm wondering about, why did the FDA stop its recording of new drug approvals? In my understanding, that was a discretion on your part and is there a reason it wouldn't implement that again?

DR. WOODCOCK: Well, the answer to the second question is, we do put a list of priority drugs. We just have two categories. Priority drugs are the drugs that are reviewed more rapidly and are thought to provide a benefit, a public health benefit or therapeutic gain over existing drugs. You're right. That's not a very large number of the new molecular entities each year. It's a fairly stable fraction of the new molecular entities, but that information is still available. So that's the answer to the first question.

The second question, on direct-to-consumer advertising, I'm not exactly sure what you're referring to. It is true that, and what Diana Zuckerman was talking about, I totally agree with her. The regs governing in print ads what has to be there, called a brief summary, and that's from the law, it says it has to be accompanied by a brief summary. So all that gibberish beside the ad is the "brief summary." It's probably true, we haven't adequately come to grips with what should be in there.

Where we have med guides, we're going to be able to have very good information in a standardized way along

with it, but often, those products that have med guides are going to be such risky products that probably will not be advertised direct to consumer. So we really, we need a better format that would accompany--at the very least, we need a better format to accompany direct-to-consumer print ads that provide this information, the risk information in a way that's comprehensible to consumers.

This has long been a source of frustration to me. I totally agree with you, but these things are not easy to get changed. This is how it's been done for a long time.

MR. BARNETT: Another one?

DR. WOODCOCK: That doesn't mean we shouldn't do it. Is there something in the works?

MR. CLEMENTE: --direct-to-consumer advertising--

DR. WOODCOCK: As I said, we've been thinking about--

MR. CLEMENTE: For 15 years.

DR. WOODCOCK: We know, okay, we know that these are not satisfactory. The brief summary is not a satisfactory vehicle for transmitting the information about that drug in a comprehensible way. We absolutely know that and I would love to get something out.

MR. BARNETT: Okay. Someone else who hasn't participated before? Anyone back there who has not? Right back there in the center.

MS. ROULEAU: I'm Mary Rouleau from the Auto Workers, and I wasn't here this morning, so if I missed something, I apologize, but--and I realize this forum may not be designed for the information I'm looking for, but here's what it is.

It would be very helpful to me as an advocate to know what kind of new safety programs you'd like to put in place for post-market surveillance--what you're doing, what you'd like to do, and what kind of dough you need to do it. I mean, we want to be your advocate on the Hill. So that's what I need to know, and if this is not the appropriate forum, I certainly accept that, but that's my two cents' worth.

MR. BARNETT: Do you want to respond?

DR. WOODCOCK: I can't give you the scoop on the dough, but let's put it this way. We had a hearing before Mr. Jeffords and Mr. Kennedy last year and it's a substantial chunk of change that we think would really be needed. Mr. Kennedy, I think, mentioned $50 million, but I didn't mention that.

We think that we could really enhance the safety net for people in this country for drugs and biological products if we had a much more active surveillance system. Right now, all we have is a passive surveillance system. It works very well to get the rare serious adverse events. In

other words, we learn very quickly about something unexpected. Not everyone in the audience will agree with this, but actually, it is true. We learn very quickly about the rare serious adverse event that's occurring, you know, the liver failure, the agranulous cytosis, the whatever that's occurring, but because physicians, pharmacists, nurses, and everybody report these to us spontaneously, in other words, voluntarily through MedWatch and they report them to the manufacturer very quickly.

But we don't have an active system out there looking at how drugs are used, how they're misused, which is, as I pointed out in my presentation, which is one of the major problems with drugs, is the way they're prescribed, monitored, and that's causing a lot of the side effects from drugs in this country. We have a lot of ideas about how that could be done, and we are implementing a few things this year, but a lot more could and should be done to manage the risks of drugs.

And we would, of course, as part of that, we would have the resources to get much better consumer information out there. We could have public information campaigns. We could really try to reach down to the level that was alluded to earlier of the average consumer out there who really maybe just watches TV, but we could reach out to that level if we were funded adequately.

We are working on this, and Dr. Henney wanted me to mention a couple of things. The Center for Devices is working on a sentinel system. They found that if they just went and educated the people in hospitals and taught them how to report and encouraged them to report and everything, they got, like, ten times more reports than what they're getting now about mishaps and the problems with the use of medical devices in hospitals. So it's clear there's a tremendous untapped knowledge and understanding out there about what's going wrong with medical devices that we could tap if we could fully implement this system. It's going to be implemented in a very small pilot way this year.

We're also working with a number of the other PHS agencies in a consortium, with HCFA, with ARC, and with the CDC, all of who get a piece of this information in their various realms. We're going to try and put our data systems together, share information, and, therefore, provide the best safety net we can with pooling our resources.

MR. BARNETT: Okay. I think we've got to move on now. Thank you two very much.

We've talked about the five centers in the FDA, but we have one more segment to go and that is a discussion of openness and transparency and that is the FDA's desire to be as forthcoming as possible in its dealings with outside organizations, and likewise to make its decision making

process as visible as possible. And so in this section, we're going to review some of the agency's history in this area. We're going to talk about the current initiatives in increasing transparency and we're also going to touch upon some of the constraints that we face as a regulatory agency in the transparency issue.

And speaking of constraints, we realize that we have made some individual disclosure decisions that may not be agreed upon by everyone. We don't want to focus on those during the discussion session. What we do want to focus on is three things: Number one, giving you a chance to comment on the transparency initiatives that you think are going to be helpful; number two, to share with us any general concerns you have about this issue; and number three, to let us know about additional steps you think we ought to be taking in this area.

And so to discuss that, let me call up Margaret Jane Porter, who is FDA's Chief Counsel, and the lead respondent will be Allison Zieve of Public Citizen's Health Research Group, and accompanying Ms. Porter will be Sharon Smith Holston, who is FDA's Deputy Commissioner for International and Constituent Relations.

OPENNESS AND TRANSPARENCY

MS. PORTER: Good afternoon. It's a pleasure to be here. As Chief Counsel, I have legal responsibility for

the agency's programs and cross-cutting initiatives and endeavors, including openness and transparency and the legal issues involved in those. I've asked Sharon Smith Holston, who's the Deputy Commissioner for International and Constituent Relations, to join me because we want to be sure to be as fully responsive as possible to issues that you might raise about specific initiatives on consumer outreach, about which I might not necessarily have the details.

It's a pleasure to be here and I hope that this final session will be sufficiently lively so that you're able to stay awake. You've seen my prepared remarks on the website, but I just want to review them again to perhaps refresh your recollection and give a chance to have a basis for comment, as I'm sure Allison will do so.

As the country's premier consumer protection agency, FDA has long recognized the value of providing consumers and other members of the public with useful information about the products the agency regulates and other FDA activities. FDA openness and transparency empowers consumers to make informed choices about their health. It helps assure consumer confidence in the credibility of FDA's processes. FDA is also a regulatory agency that must ensure the integrity of those processes and protect the sensitive information regulated entities are required to submit to it.

Even before the Freedom of Information Act was enacted, FDA promulgated regulations that attempted to balance these concerns. These FDA regulations have been for years a model for other government agencies. FDA continues to lead the world in its emphasis on openness and transparency.

It has been apparent for some time, however, that making more of the information FDA receives and generates available to the public will directly further FDA's mission to protect and promote the public health and improve our credibility with the public we serve. One of FDA's principal strengths is its science-based and risk-based approach to decision making. Open processes and objective standards and data are integral to this approach.

Moreover, consumers expect and need better and more timely information about the products FDA regulates. Regulated entities expect and need clear and transparent standards for compliance with FDA requirements. All FDA stakeholders need efficient methods of communication with the agency and FDA needs to modernize its processes so that effective and appropriate dissemination of information becomes an integral part of the agency's processes rather than an afterthought.

FDA will always want and need to protect certain of its deliberations from disclosure and it will always have

a legal obligation to prevent unauthorized disclosure of protected commercial and privacy information. Yet there is much we can do.

I don't need to emphasize the enormity of this undertaking. The amount of information FDA has to share with its stakeholders is staggering. Consider, for example, the FDA website with its more than 100,000 documents and 40-plus web-enabled databases, offering everything from patient information on new drug approvals to reports of adverse events with dietary supplements. Finding your particular needle in that electronic haystack can sometimes be a real challenge, and processing the tens of thousands of Freedom of Information requests the agency receives every year is equally daunting. Yet important progress has been made.

FDA has aggressively implemented the Electronic Freedom of Information Act, moving quickly to make available in electronic form frequently requested and other publicly available documents so that requesters have this information without needing to file separate FOIA requests and waiting for responses for them. This implementation has already led to a significant decrease in the number of FOIA requests and we hope you find it useful.

After an extensive evaluation, FDA has just launched its redesigned website, www.fda.gov, to give users quicker, easier access to the information they need. Based

on feedback from consumers, health professionals, and industry representatives, FDA's primary audiences, the agency designed a new site to place more of the most important and popular information front and center on the home page.

One of the biggest changes is the display on the home page of FDA's current news items. Reports of safety alerts and product approvals are included and updated regularly. Also featured on the new website, information on hot topics, such as cell phones and breast implants, that will be updated regularly, automated e-mail lists to which the public can subscribe, a reference room with links to FDA's Federal Register notices and backgrounds on laws and regulations enforced by the FDA, links to pages maintained by the various FDA centers, and you saw a number of those illustrated this morning, information about FDA activities, such as FOIA and clinical trials, special information for consumers, patients, women, and other audiences, an improved search engine. The site also enables users to report problems with products regulated by the FDA and to comment on proposed regulations.

All of the centers have undertaken important initiatives to maximize the availability and clarity of information about the process for review of applications and submissions to the agency in order to maximize the

availability and clarity of information for consumers and patients concerning FDA-regulated products.

For example, as Dr. Feigal illustrated in detail this morning, the Center for Devices' goal is to permit consumers to click on the name of a device and find the labeling and the basis for the approval and all of the other relevant information about a device.

A number of additional steps are outlined in the agency's report on statutory compliance under Section 406(b). There are copies of this report as you came in, and I think if you review it, you can see a number of additional steps that I won't take the time to go into now.

What are the challenges the agency faces in its efforts at improved transparency? As the agency makes more information available, the challenges of ensuring that the information is accurate and complete increase, I would say increase exponentially. In addition, the potential for inadvertently disclosing legally protected information increases.

Finally, there is the significant issue of presenting information in ways that can be useful rather than simply overwhelming the public with more data, and you heard Dr. Levin talk this morning about the challenge of providing individual consumers sufficiently specific information that they're seeking to make it really useful.

Ultimately, the solutions to these challenges lie in systematically redesigning the agency's processes using the technology that is now becoming available. An example is placing more responsibility on the submittative information to redact it appropriately, as the agency has proposed to do with the device 510(k) redaction rule. Finding the resources required to make the investments necessary in infrastructure, processes, and training to improve transparency is, of course, a major challenge.

We want to provide information that consumers want in a way that is timely and useful to you, and we welcome your suggestions on ways in which we can be more transparent, consistent with our obligations. Since there's no way the agency could or would make available all information some member of the public might want, we also need to be sure we don't create unrealistic expectations. We therefore look forward to continuing dialogue such as the one that we're having today so that you understand both what we're trying to do and the constraints under which we're operating and you have an opportunity to shape the agency's efforts.

MR. BARNETT: Thank you. Before I ask for Ms. Zieve's response, I want to clarify something. You mentioned that on the website you had information about cell phones and breast implants. There's no relationship between

the two. They're two separate topics, unless we start a new rumor here this afternoon.

[Laughter.]

MS. PORTER: Thank you very much, Mark. I was just trying to give some idea of the range. But you're right. There's no causal association.

MR. BARNETT: Ms. Zieve?

MS. ZIEVE: Thank you. I'm Allison Zieve from Public Citizen Litigation Group, speaking on behalf of Public Citizen as a whole and Public Citizen Health Research Group, as well. I'm sure that I speak not only for myself and Public Citizen, but for many consumers and consumer groups when I say that I appreciate Margaret Porter's assurances of the importance FDA places on openness and transparency. FDA documents are consumers best and sole source of objective information about new drugs and devices.

Speaking for my office, we have found that FDA's website, the information the FDA now routinely posts on its website, to be very valuable. It has saved us a lot of time in terms of making requests and the speed with which we therefore get the information. For example, the FDA now posts on its own initiative the approval packages for many new drugs, and that has been very helpful, if not always timely.

Nonetheless, without minimizing the logistical

considerations to which Margaret referred that are involved in improving transparency, I think the agency could be doing more and I'd like to offer a few examples of areas for improvement that I think should happen promptly, if not yesterday. I'll discuss a couple issues relating to the Freedom of Information Act and then I'll discuss a couple issues relating to the Federal Advisory Committee Act.

First of all, for several years, we have been asking the FDA through FOIA requests for copies of the protocols for phase four post-marketing studies required by the FDA as a condition of approval for some new drugs. Not once has the FDA responded by releasing the protocol.

In 1996, we sued the agency for the post-marketing study for the drug Metformin, and after about a year of litigation and the use of two experts appointed by the court, we got the protocol in full and $20,000 in fees. We would have rather had the protocol in 1996 and skipped the $20,000 in fees.

Since then, we have requested several more protocols, and each time the FDA has initially denied the request. When we have followed up by filing a lawsuit, the agency has then released the document without litigating. Forcing us to file a lawsuit to get information that the agency seems to agree is not exempt under FOIA is a waste of our time and resources and a waste of the government's time

and money, as well.

We were pleased when earlier this year the FDA proposed to make the post-marketing study protocols available as a matter of course in a proposed rule that would have implemented Section 212 of FDAMA. That section requires disclosure of information to identify post-marketing studies and it does not strictly address disclosure of the protocols. So we were disappointed, but we couldn't complain when the agency's final rule didn't include that automatic disclosure.

Nonetheless, even if FDAMA doesn't require disclosure, FOIA does, and I think the FDA's repeated capitulation on this issue demonstrates that. Rather than wasting the time and resources of requesters and the agency, I'd suggest that these protocols be released, certainly in response to FOIA request without the need for administrative appeals and litigation, but an even better policy would be to post the phase four protocols on the website as a matter of course, as is done with some of the approval packages.

And speaking of approval packages, I said some packages, because the FDA posts some on the website and not others. We haven't been able to figure out how the decision is made of which drugs' approval packages get posted and which ones aren't. It might be helpful to us to have some explanation of that.

But for the ones FDA doesn't publish, it's still taking us quite a bit of time when we're interested in that material and request it through FOIA to get the approval package released. Seven months has been about standard lately for getting the approval packages. We're still waiting for one that we requested in March of this year.

Second, getting back to my FOIA points, the agency continues to withhold safety and efficacy information. For instance, the agency frequently redacts safety and effectiveness information from the medical officers' reviews that ar released as part of approval packages.

For example, at present, we're still waiting to hear from the FDA in response to a November 11, 1999, request for 69 redacted pages from a medical officer review and several fully withheld pages from the attachment to that review that relate to efficacy data. Also, the FDA posted on its website that medical officers' review of the new use for a drug, Fosamax, with ten pages of safety information redacted.

In regard to two other requests, although we recently received the information, one release came only after we filed a lawsuit and both sides had filed rather lengthy summary judgment papers, and in the other case, we got it only after months and months of letters and back and forth and telephone calls to the FDA and eventually to HHS,

as well.

The repeated withholding of safety information cannot be justified under FOIA as the agency itself has recognized in numerous statements in the Federal Register, in litigation, through the MedWatch program, and in its regulation on the release of adverse event data. In addition, in informal comments with the FOIA office at HHS, these in relation to the release we were working on that I just mentioned, HHS told us that they agreed that the FDA repeatedly and incorrectly withholds adverse event data. Whether this is a training problem or a policy problem, obviously, I'm not in a position to say, but certainly these examples are illustrative of a larger problem.

Turning to the Federal Advisory Committee act, or FACA, in early 1999, my office sued the FDA over the agency's failure to make the materials sent to advisory committee members available to the public before or at the advisory committee meeting relative to those materials. The FDA settled with us by agreeing to make the advisory committee materials related to CDER's meetings available at or before the meetings, and if any of you aren't aware that that's happening, it is and you can get them on the website 24 hours or more in advance.

We agreed to settle that case without dealing with devices and biologics, but we were assured off the record

that those centers were working on the issue, and for some reason it wasn't going to happen now but it would happen, and so we put that aside. But more than one year after we settled the issue of release of advisory committee materials as to CDER, the FDA has yet to comply with this clear statutory requirement as to the other centers. Whatever the reason, the requirement well preceded our lawsuit and the FDA should make sure that the other centers, not just CDER, make the advisory committee materials available to the public before or at the relevant meetings.

Again on the topic of advisory committees, Section 120 of FDAMA states, "Each member of a panel shall publicly disclose all conflicts of interest that member may have with the work to be undertaken by the panel." This provision plainly requires public disclosure of the substance of the conflict, not just the fact of a conflict. In our experience, however, the agency has disclosed only that a member of the committee has a conflict without providing any indication of what the conflict is. This interpretation of that statutory provision seems flatly at odds with the requirement.

Let me repeat the provision, now that I've told you the problem. "Each member of a panel shall publicly disclose all conflicts of interest that member may have with the work to be undertaken by the panel." The FDA has not

only consistently failed to make the information available on its own, it has also failed to respond to a FOIA request for such information. To my knowledge, we only tried it once last August in regard to two members of one specific committee, to no avail, at least so far.

It seems to me that the agency's consistent violation of this provision could be remedied without any significant logistical hassles at all, and I'd suggest it should be corrected immediately.

While I'm on the topic of advisory committees, I want to mention one other matter because, although it's not strictly on the topic of openness, you're all listening to me.

[Laughter.]

MS. ZIEVE: The Food, Drug, and Cosmetic Act requires that advisory committees have "a representative of consumer interests." From our perspective, we see the FDA using this category as sort of a catch-all. For example, nurses are not by definition or even intuitively representatives of consumer interests, although any given nurse may be, but as a general matter, not. The FDA treats them as such. Pharmacists may or may not be representatives of consumer interests, but the FDA treats them as such.

In one instance, the FDA chose as a representative of consumer interests an academic pharmacist whose work was

as a researcher for pharmaceutical companies. That person seemed to be a representative of industry interests.

So I would urge the FDA to take a narrower view of that phrase, representative of consumer interests, what I would call a truer view of that phrase.

I began by applauding Margaret's comments and then I proceeded to criticize the agency on openness, and if that doesn't sound too inconsistent, I'm actually sincere on both points. The FDA has made good use of its website. It's been very helpful to us. I agree with Margaret that the FDA has been ahead of most other agencies in terms of FOIA regulations and often, in our experience, response time to FOIA requests. But at the same time, it has been recalcitrant in several areas as to which the law seems clear which causes a great deal of wasted resources, both ours and the agency's.

So I hope that in the remaining time, Margaret or somebody can respond to some of my comments, and I thank you all for letting me speak to you today.

MR. BARNETT: Thank you.

Would you like to add anything?

MS. HOLSTON: No.

MR. BARNETT: Okay, good.

[Laughter.]

MS. HOLSTON: In the interest of time.

MR. BARNETT: In the interest of time. Okay. Let's open up the floor for questions and comments. Yes, back here on the left, whoever had their hand up there. I saw a hand.

DISCUSSION

MS. SMITH: Thank you. Fran Smith, Consumer Alert. And as a representative of a consumer group, I'd also like to ask one of the respondents a question. Consumer groups are special interest groups in many cases. Some are allied with unions. Some are allied with trial lawyers. Some receive government grants in a significant way.

Do you think that those sorts of relationships should be disclosed when people are asked to serve on advisory committees with the FDA and other agencies? I think that's an important question, because consumer groups are special interest groups, just as any other civil society group. By excluding yourselves from requirements that everyone else must follow, it seems to be a bit unfair. Thank you.

MS. ZIEVE: I'm not sure what the questioner meant by requirements that everyone else must follow.

MS. SMITH: Conflict of interest, disclosure.

MS. ZIEVE: I think the statute requires disclosure of conflicts of interest from all members of the

advisory committee.

MS. HOLSTON: But I think the statute is specifically referring to financial conflicts of interest and that's what people are obliged to disclose. I'm not sure if you're saying that there are other kinds of conflicts that are not necessarily limited to financial conflicts, and that may, in fact, be the case, but that is not what the statute requires. And so to disclose that one is a member of a particular group that may have a particular perspective, while it might be interesting, it's certainly not a requirement that FDA could enforce in terms of its advisory committee meetings.

MR. BARNETT: Over here? Yes, sir?

MR. DRUKER: Steven Druker with the Alliance for Bio-Integrity. I have a follow-up question to an earlier statement I made on genetically engineered food, but it deals directly with the openness and transparency issue.

According to the FDA, genetically engineered foods are all on the market because each one can be presumed generally recognized as safe. According to the agency's own regulations, that means that each one of them has to have been demonstrated safe through the same quantity and quality of evidence that would have been required to establish it safe as a new food additive.

So I'm asking, especially because three of the

experts in our lawsuit have submitted declarations to the court saying they are not aware of any information, any evidence demonstrating that even one genetically engineered food is safe, let alone the whole lot of them, where is such evidence and make it available so that the independent experts who are supposed to be reaching consensus on it can do so.

And secondly, related to this, Commissioner Henney, on May 3 of this year, you declared FDA's scientific review continues to show that all bioengineered foods sold here in the United States today are as safe as their non-bioengineered counterparts, unquote. But The Lancet shortly before then had reported that in January of 1999, FDA issued an official statement saying FDA has not found it necessary to conduct comprehensive scientific reviews of foods derived from bioengineered plants consistent with its 1992 policy, unquote.

My question, therefore, Commissioner Henney, is between January of 1999 and May 3 of 2000, what kind of comprehensive scientific review did the FDA, in fact, conduct?

DR. HENNEY: The kind of review that the FDA has conducted with all genetically modified foods that are now on the market and that are available for food consumption were the type that were contemplated in our original policy,

where we have what has been a voluntary consultation with industry where data may be shared with us in terms of what they intend to market, and as we see issues that may give us either safety concerns or the need to label products in a specific way, that has been done, and that has been done ever since that policy was enacted. So we didn't have a window of just six months that we were looking at.

I think what The Lancet refers to is that--and our policy never contemplated it--is that the genetically modified foods were to be reviewed in the same way as a food additive was.

MR. BARNETT: Thank you. Let's have one from the lady here. Yes?

MS. HOCHANADEL: Again, my name is Deborah Hochanadel and I'm with the Massachusetts Breast Cancer Coalition and I'm going to name the other members of a coalition that we are with because I'm speaking for all of them as one voice and you need to know all of those members: Boston Women's Health Book Collective, Breast Cancer Action from California, Breast Cancer Action Montreal, Center for Medical Consumers, DES Action, Massachusetts Breast Cancer Coalition, National Women's Health Network, Women's Community Cancer Project, and Working Group on Women and Health Protection. I just tell you who we all are because I'm speaking for more than one voice. That's why I raised

my hand to speak again.

What I want to speak to right now is conflicts of interest in the FDA advisory committees. A great deal of attention has been paid in the media lately to the fact that so many of the scientists and researchers on FDA advisory committees have real or apparent conflicts of interest. The public's faith in the decisions made by the agency are undermined by these conflicts, and you can see that here, and we believe they need to be addressed openly by the agency and corrected.

One aspect of this issue that is of particular concern to us relates to the possibility of conflicts of interest among consumer representatives to the advisory committees and among those who present testimony to the committees. Increasingly, groups that purport to represent a consumer viewpoint are financed in whole or part by pharmaceutical companies or manufacturers of devices that come before the FDA for approval.

The FDA should strengthen its requirement that all those who purport to represent a consumer point of view to the agency disclose whether they receive funding or other assistance from entities with economic interests at stake before they testify before the FDA. These conflicts of interest, like those involving the scientific and research community, need to be addressed and resolved by the FDA. We

look forward to working with the agency to develop strategies for doing so. The interests of consumers are very different from and frequently opposed to those of industry.

No group receiving 100 percent of its funds from industry can reasonably be expected to represent consumer interests at a policy forum. We question whether any organization that receives more than, say, ten percent of its funding from industry could do so.

In order to strengthen the FDA's conflict of interest policies, we urge that as a condition of participation in FDA public forums or the submission of written comments to FDA committees, all consumer representatives be required to disclose the percentage of annual funding that their organization receives from industry. We also suggest that the FDA separate its public comment time during advisory committee meetings into industry-free and industry-support segments, requiring all representatives of groups that receive ten percent or more of their annual funding from industry or any funding from a company with a matter before the committee, for that matter, to reserve their comments for the industry-supported segment of the meeting.

And I'm closing now, don't worry. When the FDA appoints consumer representatives to serve on agency

committees, those representatives should never have a financial relationship with the industry being discussed by the committee. That seems like a no-brainer to me. If a financial conflict of interest arises for a consumer representative during the course of that representative's term, the FDA should appoint a temporary consumer replacement for that meeting.

Again, we would love to work with you on this concept. Thank you.

MR. BARNETT: Thank you.

It's time now to go to our last segment in which we're going to call back the center directors and have them talk about what they've heard today.

But before I do that, let me see a show of hands. How many people here are from a consumer organization that want to speak and that have not been called on yet? Raise your hand if you're in that category. How many?

[Show of hands.]

MR. BARNETT: All right, one, two. Other than that, if you are from a consumer organization and you are here today, you have already spoken? Fine. So for those two people, let's reserve a little time when we do that.

I'll have the office directors come on back up. In the meantime, the rest of us can take no more than five minutes to just stretch while we change sets here.

[Break.]

MR. BARNETT: Let's start out, then, with a brief comment or question from the two people who raised their hands who had not yet had a chance to speak, and where are they? Yes, ma'am?

MS. DUNCAN: I'm Janel Duncan and I'm from Consumers Union, and actually, this question was prompted by the last session having to do with transparency.

I know that a lot of the information received by the FDA and analyzed by the people in the FDA, the scientists and others, is submitted by industry, and the information that is allowed to be released to the public is information that is not privileged. Often, the information that--the determination or the designation of the information as privileged, a trade secret or confidential commercial information, is done by the sponsor or the person submitting the information. I think it's become apparent that a lot of the information submitted as such doesn't necessarily qualify, and so that information, it's very difficult to have relief.

I wonder, what can be done to better ensure that there's not an abuse of that designation to make it easier to get information that is legally entitled to be released to the public?

MR. BARNETT: Who wants to respond?

MS. PORTER: The questioner raises an important question. As I referenced in my prepared remarks, in order for the agency to meet its desires to make the reams of material it receives more readily available, we're going to need to rely, in part, on the sponsors' designation. But we have the ultimate responsibility for assuring that material that is withheld as confidential commercial is, in fact, protected by law.

MR. BARNETT: Okay.

FLOOR QUESTION: I'm a consumer member of an advisory panel. I was with CDER. I still am with CDER. And I have to say a few things positive about FDA, and those people who know me best know that I speak my mind.

First of all, you have a wonderful new label for OTC. I hope you use it for prescription drugs.

I am impressed by the staff and the work that the staff does. I think they are underpaid and overworked. I'm impressed by the sincerity of FDA, but I do have a lot of problems, and here I begin. But I should tell you, so you know, I have an annuity from my husband, who was at NIH for 41 years. I have my retirement from Montgomery County Office of Consumer Affairs, and nobody, nobody can tell me what to do if I think it's against the thing I'm supposed to do, and it is an honor and a privilege to serve on an advisory panel.

I saw my husband through the age of the golden years of science. It is no more. It's rough out there. And as far as I'm concerned, politics and science give me a stomachache.

I think the thing that I'm very concerned about is, first of all, if I could do the advisory committees, I think there should be two consumer members. One consumer member is not enough. Maybe in my case, one is enough, but in some--

[Laughter.]

FLOOR QUESTION: And you have to have humor about this. Sharon, don't you dare laugh. If you don't have humor, then you don't belong dealing with anything because you lose your sense of perspective.

I think there has to be better training for some exec secs and some of the chairmen. I served on a committee recently on PPA and I'd like to talk about what I saw there. When I asked to see a consumer insert, I was told by the chairman, "Why don't you go to the gift shop and buy one?" Now, that's disrespectful to a consumer member who is there to serve.

PPA, to me, phenylpropanolamine, was very interesting, that all kinds of scientists appeared to represent industry. Research grants are very hard to get now. They might even be harder if they don't come through

with an NIH budget. So everybody is competing for money from industry.

I am concerned about that pressure that's brought to bear when these consultants come in in front of the FDA. PPA, there was a man--and I'd like to tell you a few stories, because this is a reality--who runs a diet clinic for one of the universities. He doesn't need PPA to get people to lose weight. All you have to do is close your mouth. But he came to represent industry that he needed PPA.

And then all these so-called scientists came to defend the use of phenylpropanolamine, and I'm thinking, this isn't an antibiotic. This isn't going to make any difference in anybody's life if you don't have it. And I'm really worried about getting research grants and it affects consumers directly. My dream is to have a pool of money given by industry, not directly by any name, and people who applied to get that money, because once money is attached to a research grant, I'm very concerned.

I'm worried about post-marketing. I think it should be stringent. I think they should be monitored for one year, absolutely, to see what's going on, and they must report. And I'm also concerned about off-label use. That's another thing that worries me.

I think there should be more clinical trials in

communities where they have health clinics, in poor communities, where you get diverse cultural, you get gender. I think that the trials are done maybe among people who don't need the trials as much, but let's go into the inner city and let's bring some health care to the inner cities along with doing clinical trials.

So I think that there's a lot to do and not enough money, but I think I want full disclosure and that truly worries me now, is the grabbing from money to do research. I think something else has to change.

And I think that the other thing is, industry wants to extend their patents now so they come to extend their patents. I mean, there are more important things for them to do than worry about extending their patents and, therefore, making generics less expensive for people.

So I think that there are so many issues, and this nice lady back here, she really struck me. She really was talking about consumers. I'm a consumer member, but this isn't my world. The world is out in the inner cities. The world is among the poor. The world is among people who don't have websites. The world is about those who really need help, and I hope that we can reach through these clinical trials more needy people, and thank you for allowing me to make my speech.

MR. BARNETT: Thank you.

I think--was there one more person who raised their hand earlier that had not had a chance?

[No response.]

NEXT STEPS

MR. BARNETT: Good. Okay. That being the case, let's go back to what we heard earlier today and ask the center directors that are up here to respond--I'm not going to call on anybody in order, you can just do it voluntarily--as to what you heard today from your responder and also what you heard from the audience. And, by the way, Dr. Feigal changed his appearance to Dr. Lee Joseph. Dr. Feigal had to go back. Dr. Li Joseph, who is Director of the Office of Health and Industry Programs in Dr. Feigal's center is here in his stead. So, anyway, who wants to begin? Yes?

DR. ZOON: Thank you, Mark. I appreciate it. Since I was first on the agenda this morning, I'll take the opportunity to be first in making comments. And those nanobots really do wonders.

What I'm going to try and do, Art mentioned a number of different issues related to CBER and what I'll try to do is cluster them so my remarks aren't too lengthy because I want to leave plenty of time for my colleagues to comment, as well, and I'll try to touch on a number of issues as they relate to earlier comments from the audience.

One, there were a number of issues, Art, that you raised on budget and staffing needs of CBER, both in general to meet the scientific challenges as well as dealing with some very specific items, including gene therapy, and I think we would be very happy to discuss with interested parties at a separate meeting maybe workload issues, what it would take for different models, because some of these things have different needs. And I think in fairness, not to not give you a direct answer but to really discuss it in greater depth, I think that might be a more appropriate environment in which to do it and we'll be happy to discuss that.

The other issue that you raised dealt with ethical issues. What perhaps I'd like to do is say that this is a new emerging area and we're very much in tune with the increasing scrutiny from an ethical perspective. We, as I mentioned, try very hard to get that representation on our advisory committee, depending on subject matter that might be appropriate for that. We're also often asked to participate in the National Bioethics Advisory Committee, which we participate in.

We think that's a very important piece for a broader public scrutiny, and that would include everything from specialized new medicines through general issues on clinical trials and human subject protection, which covers

the gambit. I think those are very important. We look for opportunities to get both specific and broader public health input.

There are also other advisory committees, not just FDA advisory committees but now Department advisory committees dealing with blood and one that's being formed on xenotransplantation, which for those who may have come late is the use of animal organs or tissues and cells in humans as an alternative to a short supply of human organs and tissues.

Again, so there's a great deal of participation. There's ethicists involved. So we hope that in this way we'll get broad input into those matters. But there may be still more to do in this area and we will be vigilant in looking into that.

Human subject protection is a big area, one I know that Dr. Henney feels very strongly on and FDA has some very specific initiatives underway looking at a variety of different areas, including issues related to institutional review boards, as well as working with the Department of Health and Human Services on issues of informed consent, working with the new office headed by Greg Koskie dealing with human subject protection. So we take this very seriously, both as what we can do as an agency, and it doesn't affect just CBER but all the agency centers. We are

a player in that and feel very strongly that we have an important role there.

Blood, a very important area. As you mentioned, we established a blood action plan in 1997. I can say that blood is safer today in the United States than any other time in the past. Can we do better and there's more to do? Yes, and we are constantly vigilant. We are looking at new technologies, such as nucleic amplification testing to improve the detection of adventitious agents in the blood. We're also looking at better ways of improving donor qualifications and questions so that they're more understandable to folks who are donating blood. There are many areas.

The blood action plan actually touches on all of these areas with respect to actually ensuring a blood supply, an adequate blood supply, but making sure that blood supply is safe. If there are compliance issues, we are not shy on taking action. Those of the blood industry that know us know that we expect standards to be met and that is clear. But we also recognize our role in working not only as the FDA but with the rest of the Public Health Service, which Dr. Satcher is head of the Blood Safety Committee, working with CDC and NIH in making our blood supply in this country as safe and available as possible.

With respect to PDUFA III, as you mentioned, we're

starting negotiations on that. PDUFA has provided the agency additive resources above the base resources for new drug and biologic review. My sense, and the question you asked, you know, are there good points and bad points, in my opinion, there have been many good parts to PDUFA about helping the agency get resources that weren't available to us to do some of the enhanced review processes that we have needed. But as cost-of-living increases were not realized in other areas, our ability to do activities not covered by PDUFA were challenged, and I think that dichotomy still remains a challenge to not only our center but to the agency as a whole and it's something that we are trying to open up in a broader process to get the input to reflect a broader constituency on how to proceed with PDUFA III.

With respect to--

MR. BARNETT: We're pushing close to closing time and I want to get enough time for other folks.

MS. PORTER: Just one last comment on vaccines--

MR. BARNETT: Okay.

MS. PORTER: --because I know that was--if I can. Is that okay?

MR. BARNETT: You may. You may.

MS. PORTER: Thank you. One last comment on vaccines. Vaccines are clearly a very important product area for CBER. We want to engage the community in

understanding their ability to report adverse events, clearly because vaccines are preventative medicines. In many cases, we give them to our babies and we want to make sure that our babies are safe and protected. The more input we can get from physicians, from parents themselves to provide data into the agency is extremely important to us.

And so I would encourage all the consumer groups, if we could work with you to encourage that kind of input into the agency, we would value that. And we're also working with the Center for Drugs on looking at better adverse reporting systems, as well as working with the Center for Disease Control to enhance the information coming into the agency, particularly with blood and vaccines, but working with the Center for Drugs on other therapeutics. And I'll stop there.

MR. BARNETT: Okay. Let me ask, as we go down the line, to pick out a couple of items to zero in on that you heard about today rather than being comprehensive. Li? Or you don't have to comment at all, if you don't want to.

[Laughter.]

DR. JOSEPH: I will make it very general and brief. Specifically, I heard a request for a very specific kind of information for consumers that is easily accessible, easily found, and that contains the details and/or contact people so that if there are questions, there's a means of

following up. We've been working on that very item because we've been as equally frustrated within the center itself. So that is obviously one area that we are addressing and we will continue to address.

Although I realize not everyone uses the web as frequently, but we're trying to make that very user friendly and very plain terminology so that it's easily understood. But we're also doing a lot of work with multiplier groups, developing materials in very simple, plain, direct language and asking them to provide them to the constituents because we can't get to everyone.

And I think my last point was in terms of the radiation issues that were addressed. Dr. Feigal did not mention that because of--he did mention that because of the decreased resources in this area, we have taken a step back and we've begun to revitalize the radiation program and are thinking of devising an algorithm that helps us prioritize those very issues that some individuals brought up here that we need to address. And so we'll direct what resources we have to addressing those high-priority issues based on certain criteria. Thank you.

MR. BARNETT: Joe?

MR. LEVITT: I have five points that I thought I would mention in way of summary. Number one is Michael Jacobson clearly recognized the need for increased FDA

funding and on a scale different, meaning larger, than we've been experiencing even recently. He called for a doubling of the foods program over four years, including both headquarters and the field. And he expressed some frustration at, notwithstanding recent funding, and he, having just heard my presentation about the cost of living, realized that's what had happened.

But within foods, we have had the benefit of increases over the last four years averaging about $24 million a year between CFSAN and the field, but our cost-of-living increases are about $12 million. So, you see, we're only netting about 50 percent and people expect to see the full benefit of 100 percent and the 50 percent leaves you with a dissatisfied feeling externally. I can tell you, internally, it does, too. But nevertheless, I think the funding issue was the first thing he said.

Second, Mike had a long list of "to do"s and really covered all the areas that I had mentioned in terms of food safety, food additives, dietary supplements, biotechnology. A lot of the items that he had listed, we have on our "A" lists or our "B" lists. A lot of it has to do with time, attention, and priority.

What I didn't say this morning, but the analogy I usually give, is I think it's better for FDA to pick a few boulders and move them up the mountain and over the

mountaintop rather than putting 100 pebbles up the mountainside at one mile an hour. I like to kind of see results and I think the public wants to see results. As somebody referenced the food label as an FDA success, that was a massive effort but over a small number of years which got that done and over the mountaintop. I'd rather what we do, do well and some things not at all rather than do everything poorly, and I think too often sometimes we try to do everything, but it means we do everything poorly, and so we're doing our best on that.

Third, from the public comments only reinforce what we've been feeling over the last year, that every question was on food biotechnology, that that is a dominant public interest issue. We are devoting a lot of time and energy to it. You heard me respond to what we are doing.

Fourth, there was one comment earlier on in one of the earlier sessions that I've been thinking about all day since I heard it, which was a--it was during the device session and it was a woman who just spoke a moment or two ago who made reference to the fact that the web, while we all feel, hey, we're putting all our stuff on the web, the web doesn't reach everybody, and as I sat here it struck me that so much of our food information, especially food safety information, is designed to reach everybody. How do we do that?

I'm looking back to the "Fight Bac" program. It's a major public/private partnership involved in, if you will, marketing that message. But are we really reaching consumers, and if not, what are the ways that we could reach consumers? I don't mean consumer advocates, I mean consumers, you know, the 200-plus million that need information about food.

We recently did a study of food safety practices in the kitchen where somebody who was given a grant from us went and videotaped--you may have seen this on TV--videotaped people in their kitchen. Now, they knew that they were being videotaped. They didn't know that they were being videotaped for food safety. They thought they were being videotaped, I guess, for cooking technique. But nevertheless, they knew they were being videotaped, and yet they on videotape show every mistake in the book in terms of good hygiene in the kitchen, even with all the awareness we've tried to have. And so how we really reach everyday consumers is to me an important take-away that I didn't expect to get coming in today, but I'm glad and I'm thinking about it.

And finally, there was a reference near the end of the day in another context, I think it was direct-to-consumer advertising, about that FDA should rob Peter to pay Paul because this is so urgent. And just one, if you will,

one of Margaret's terms is push back a little bit on that, because, to be honest, we are the world's masters at robbing Peter to pay Paul. There is nobody in the world better off than the FDA at that.

And what we're finding is that is short-term gratification for long-term cost, that it is not worth it over the long run and we're realizing it, that the public really needs, if you will, both hands, and what happens when you rob Peter to pay Paul, it's like doing your job with one hand behind your back. It's good for a while, but then you lose the benefit and we are really feeling that.

And so, I think, as we plan our budgets, plan our programs, plan our priorities, it should be what we do, do it well, give your whole all to it, and not think that we can just pull a little from here, pull a little from there. We ought to do it right, because I think that's what the public wants and deserves.

MR. BARNETT: Thank you, Joe.

Dr. Sundlof?

DR. SUNDLOF: Yes, I'll respond to some of the questions, primarily the ones that Richard Wood proposed, and in, I think, in just about every case, I agree with the comments made. I thought they were very insightful.

Basically, I think I heard that there was general acceptance and people were pleased that we had taken a very

proactive approach to dealing with the issue of antimicrobial resistance by issuing guidances and moving to withdraw those drugs that we think are of greatest concern, but that we need to move faster on it, and I certainly can understand the feeling of frustration with that because I experience it every single day. We would like to move as fast as possible, but having this input certainly helps us in making that happen back at the office.

More responsiveness to citizens' petitions, I think I heard that from not just CVM people but for some of the other centers that were not responding in enough time to citizens' petitions that are considered very important by the consumer community, and again, take that to heart.

We need to have--one of the issues that I really wanted to respond to is the need to have more data on sales of antimicrobial drugs so that we can get a better idea of what the use of these drugs in animals is doing in the human population. We are in the process of writing a regulation to do just that and we are fairly far along on that. So within a relatively short period of time, you should see a proposed regulation and proposed rule coming out that would specify exactly the kind of sales information that we are going to be requiring on antimicrobial drugs that are used, especially in food-producing animals. I heard that consumers need to be involved in all of the discussions on

antimicrobial resistance and we certainly welcome that.

One other issue, and I thought this was good and I hadn't really ever thought of it in these terms, but we mentioned that we had implemented processes to expedite some of the review of the drugs, and the concern that was raised by Richard was that you're trying to get them through faster, but if you have problems, you have a hard time getting them off the market. And are you doing anything on the post-approval side to expedite that process? That's where we may really need some strong support from the consumer community in trying to make that process a little bit easier. But that would be a tremendous help for us.

The last area was on the BSE, the bovine spongiform encephalopathy, and the needs to start taking stronger enforcement actions against those companies that are found in violation, and I think that has been our thought, too, that we've gone through this education period where we've gotten out and we have done the inspections. We've had an impact in people when we reinspected, that the majority of those people have come into compliance, but there are still some people out there, some firms out there, that despite our efforts have elected not to comply and we need to take stronger enforcement action against those and I feel that that's certainly justified.

We'll be having many meetings with the people on

this issue because of the increased concerns that have been raised over in Europe and the concerns that I have about problems that have been created in Europe moving across the Atlantic into this country. It's an issue that we consider to be extremely important, and I think I'll close there.

MR. BARNETT: Okay. Janet?

DR. WOODCOCK: All right. For the sake of brevity, I'll respond to Cindy's five goals that she put forward for the following year and also a little bit about some of the Freedom of Information issues for CDER.

The first goal was that consumer groups should have more input, and actually, we've been seeking consumer input this year, CDER had, and we went about a process. We weren't necessarily seeking consumer advocacy group input. We went around the country and had meetings and sought consumer input, and that sort of reflected some of the things that I said about what we find that people actually want.

But it isn't effective for us--because there are so many people in this country, we can't reach out to everyone of them all the time and we need to work through the consumer groups. It sounds like--we certainly respond when people approach us, but it sounds like we need to institute some more formalized process with the consumer groups. Since we're probably not going to go on a United

States tour again this year, I think we can do that and try to improve access to the center for the consumer groups.

The issue of the advisory committee reps is a different and complicated one and I will leave that to Sharon to talk about. But we can put together a better process, I think, for drugs.

The second one was, can we put more guidelines, particularly in areas--it's easy to get guidelines out when there's a lot of activity in an area and people are clamoring, but I think we have had success in the past of putting out a guidance in an area that we felt was underserved and stimulating research by sort of showing people what the goalpost is and what you have to do to get the ball over the goalpost. I have been personally urging our staff to publish these guidances, with signal lack of success in some instance.

There is a topical microbicide working group, for example, and what they tell me is they feel there isn't enough data. It's sort of the chicken and the egg problem. You don't have enough data and you haven't tried it very much in humans and you don't have enough data to design the standards by which then you could judge other folks. But I will go back and talk to them, and also, I think we will have emphasis on this.

The related issue of the surrogates for approval,

we actually haven't adopted very many surrogates for efficacy lately. Most of those were in the far past and most of them have been validated. Both cholesterol lowering and fracture rate, say, for osteoporosis have been validated by trials, by mortality trials that have been done or bone fracture rate trials that have been done and shown for some products that they do have an effect. Also, of course, the HIV model, the surrogate endpoints have been validated.

So I'm not sure. I think, in general, and I was having a discussion with--we didn't mention pediatrics today, but that's a huge area. We're having a tremendous sort of blossoming of trials in children. We've already learned crucial information about the use of drugs in children that we wouldn't have known if these trials hadn't been done. In a number of cases, that information has gotten on the label. So that is another area in which we're going to need many more guidelines. We need a lot more information. It's a very important area.

But what I was going to mention is that, just like in the adults, one of the issues is we don't have long-term information. We don't have information on the long-term effects of the use of drugs in children, nor in what Cindy was talking about, do we get information often on long-term use, either effectiveness or safety, of drugs in adults, and that's another area that I see in the next decade or so

really is going to require some work, and the pediatricians are certainly thinking about this.

Post-approval risk management, you urged an increased profile there, and certainly we agree with that. I think we at FDA agree with that and have said that in order to confidently approve drugs, we have to have confidence that the system is going to be able to manage the risks of those drugs and that's an issue we have. As I said, the people in the health care system are already pushing back on us about this, so this is going to really be a back and forth. This is going to be a real challenge to go forward on. But certainly everyone in CDER, we're realigning ourselves and our organizations around management of risk and that's something that we can all understand and understand how we need to go forward on that. So that's been very positive for the center.

Prohibit direct-to-consumer advertising--that reminds me, one of my staff once told me--we were having a lot of problems with visas and they said, "Dr. Woodcock, you just have to change the immigration laws," and they really felt that I had the authority and the power to do that because I was a center director. Obviously, I would know how to do that.

[Laughter.]

DR. WOODCOCK: I mean, I'm not saying that this

couldn't be done, but I think that there are many other players and legal issues involved in advertising other than what the FDA has authority over. We certainly hear you about DTC and we're willing to meet additionally with people who are interested in that. And as I said earlier, of course, I think that the current brief summary isn't satisfactory and I need to check on how we're doing on that.

And finally, the last one was improve our consumer information. Yes, we agree. I mean, everybody else has said that, too. We agree we need to do that. Our scientists are not real good at this. Their idea of consumer information would just leave you falling down laughing. It's like the post-graduate level, and what do you mean, hyperwhipademia [ph.]? And they have to put all these long words in. So we really have had to hire new people and everything to actually translate this information into things that would be comprehensible to anyone because we can't get our scientists to just write this down. It doesn't make any sense.

So we have some challenges in consumer information, but I think we're on the right path and we appreciate the feedback that you think it's valuable, but it is another resource effort for us. We're trying hard. We aren't doing as well as we should. We're kind of wimpy at this, but we can get better, and if it's valuable, we will

do it. We will make it better.

And we know we need to make it available in ways other than on the website and via the Internet. We know that, and actually, we can partner with people to make that happen. We have done some consumer campaigns ourselves, such as on GHB and on drugs on the Internet that have really penetrated, with pamphlets and leaflets in different ways into our society.

And finally, on the FOI issue, yes, we do have some problems. For CDER, at least, the information, the redaction is a problem. We're behind. Our FOI people are in a hallway. They're crammed into a hallway. Their conditions are terrible and they're behind on getting this stuff redacted. But we have a legal obligation to do it correctly. We can't release information that is illegal for us to release, and so each of those pieces of paper have to be read by our FOI people to make sure they're correct, and so we have a tremendous burden and we haven't been able to keep up with it. That's the bottom line. And we're going to try some additional efforts, and I think you'll see an improvement in our services here, but it remains a problem for us. I freely admit that.

MR. BARNETT: Thanks. Let me ask sharon and Margaret, although they're sitting at opposite ends of the table, let me ask them collectively if they want to respond

to what they heard today.

MS. HOLSTON: I did want to respond specifically to the whole issue about conflict of interest for-- particularly for consumer representatives on advisory committees, and this is a topic that really has generated a great deal of discussion within the agency. It is something that we're actively working on now with the members of our consumer consortium.

And the more I listened to what people were saying, the more I was beginning to think maybe we should go back to square one and think about, what is the purpose of having a consumer representative on the advisory committee? What is the role that we expect that individual to play, and then try to decide who is the best person to fill that role.

Sometimes, it may be that the best person to appropriately represent the perspectives of consumers may not be, in somebody's definition, "a consumer." They could even be, God forbid, an academic whose institution may have some ties to the regulated industry, and I'm not suggesting that that's the way we should always go, but I think it's a question that we have to ponder very carefully and decide, who do we want?

And if it's someone who has absolutely no financial ties of any kind to the regulated industry, then so be it. We just have to figure out how to find that

person and get that kind of person on our advisory committees. So maybe the answer is, we just need a bigger pool of people to pick from. But it is something we're grappling with and we're going to be doing a lot of work on it.

DR. WOODCOCK: Can I say one thing about that? With regard to the people who spoke up about the conflict of interest on some of CDER's advisory committees, we looked back at this because it was in the press and this all goes to that people think there's a bias towards approving drugs and everything. Sixty-four percent of those were connections that got waivers, were connections with a competitor to the drug being under discussion. So it cuts both ways. Competitors have to be--people with ties to competitors, those have to be scrutinized as well as the ties to the sponsor company under evaluation.

MS. PORTER: Let me respond, too. Allison had to leave, but I do want to certainly agree with the overall goals that she articulated of consistency and predictability and responsiveness in the agency's FOIA process. I think, as Janet has alluded to, there are significant challenges in becoming more responsive and still meeting our legal obligations, but I think everybody agrees with the seriousness of the problem.

I would also agree that we should not spend

resources on litigation that can be avoided. It's time consuming and very intensive for everyone.

I would emphasize, as Dr. Woodcock did, that there are legitimate protected interests here and sometimes it takes a lot of time and effort and careful negotiation between the requesters and the submitters to be sure we get the right resolution.

MR. BARNETT: Thank you. And finally, let me ask Dr. Henney if she has any final comments to make.

DR. HENNEY: This has been a good day, and as I said at the beginning, I think that it is just a start of what I think that we need to keep doing in terms of both listening, being open as an agency to not only how you view us but how you see our own priority setting.

I think that we didn't assume that the day would be comfortable. We thought that you would come in with ideas anywhere from the prodding to the provocative, and you've done that. I think that you've been very candid and I hope that what we have done is listen with both open ears and open minds. I think many of your ideas clearly, just in terms of the comments of the center directors, have been heard.

I think probably the biggest frustration that I have sensed in the room, that we didn't have more time to hear from more of you about more issues that you wanted to

weigh in on. I think you know who we are. I think that, as you have follow-up to this particular meeting, I hope that you'll channel that either to the right person or at least through Sharon's office so that we can hear the additional kind of comments that you might have made had we had more time in this day.

I think one thing that I heard was not only our desire to keep doing this kind of thing on a periodic basis, but perhaps even a format suggested that came out fairly early by Art, who suggested that we see this more as a plenary and that at some point we arrange conversations that have more of a break-out or a dialogue or freely roving around from room to room so that you can register the things you want where you want, or something like that.

I don't think that we are inhibited by how we choose to construct the next session. I hope they'll continue to be constructive. I would probably have us leave on probably one of the greatest philosophers of the 20th century, the words of, I think it was Will Rogers who said, we're on the right track, but it's not enough to be on the right track. We need to get moving.

So we all agree, I think, that this has been a reasonably good day. We've heard each other, I believe. We just need to keep moving towards the goal that we all have, and that's the best of public health for this country and

really the world. So thank you very much.

MR. BARNETT: Thank you, Dr. Henney. Thank you to everybody on the FDA panel, and thank you all for coming and for your good questions.

[Whereupon, at 3:50 p.m., the proceedings were adjourned.]

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CERTIFICATE

I, **THOMAS C. BITSKO,** the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

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